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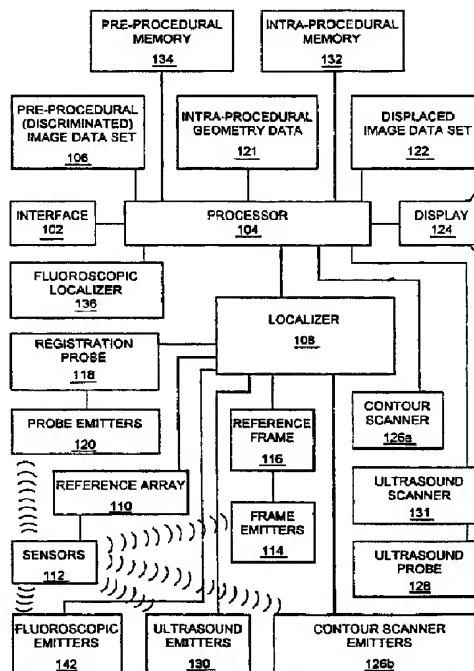
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(54) **SYSTEMES DE GUIDAGE CHIRURGICAL COMPRENANT DES CADRES DE REFERENCE ET DE LOCALISATION**

(54) **SURGICAL NAVIGATION SYSTEMS INCLUDING REFERENCE AND LOCALIZATION FRAMES**

(57)

This invention is a system for use during a medical or surgical procedure on a body. The system generates an image representing the position of one or more body elements (10), (20), (30) using scans generated by a scanner prior or during the procedure. The image data set has reference points (10A-30C) for each of the body elements, the reference points of a body element having a fixed spatial relation to the body element. The system includes an apparatus (108) for identifying the relative position of each of the reference points of each of the body elements to be displayed. The system also includes a processor (104) for modifying the image data set according to the identified relative position of each of the reference points during the procedure. Also disclosed are devices for use with a surgical navigation system having a sensor array (110), (112) in communication with the device to identify its position.



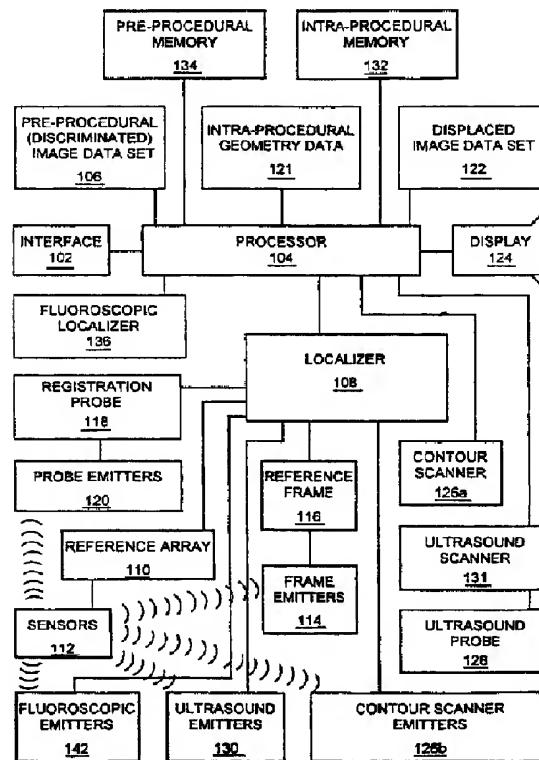


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(57) Abrégé/Abstract:

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(57) **Abbrégé(suite)/Abstract(continued):**

procedure. The image data set has reference points (10A-30C) for each of the body elements, the reference points of a body element having a fixed spatial relation to the body element. The system includes an apparatus (108) for identifying the relative position of each of the reference points of each of the body elements to be displayed. The system also includes a processor (104) for modifying the image data set according to the identified relative position of each of the reference points during the procedure. Also disclosed are devices for use with a surgical navigation system having a sensor array (110), (112) in communication with the device to identify its position.



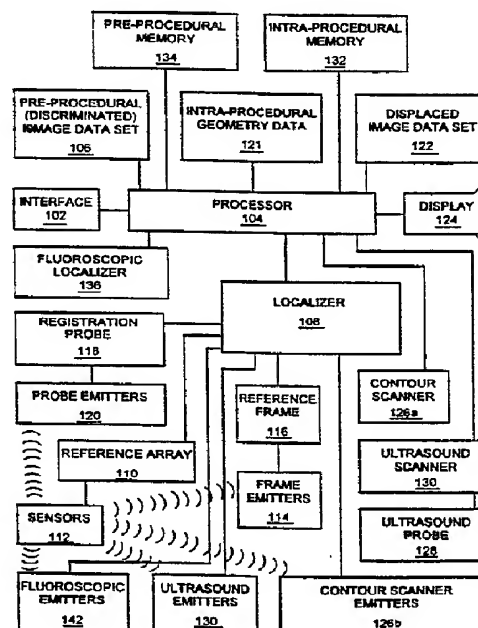
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(54) Title: SURGICAL NAVIGATION SYSTEMS INCLUDING REFERENCE AND LOCALIZATION FRAMES

## (57) Abstract

This invention is a system for use during a medical or surgical procedure on a body. The system generates an image representing the position of one or more body elements (10), (20), (30) using scans generated by a scanner prior or during the procedure. The image data set has reference points (10A-30C) for each of the body elements, the reference points of a body element having a fixed spatial relation to the body element. The system includes an apparatus (108) for identifying the relative position of each of the reference points of each of the body elements to be displayed. The system also includes a processor (104) for modifying the image data set according to the identified relative position of each of the reference points during the procedure. Also disclosed are devices for use with a surgical navigation system having a sensor array (110), (112) in communication with the device to identify its position.





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SURGICAL NAVIGATION SYSTEMS  
INCLUDING REFERENCE AND LOCALIZATION FRAMES

Background of the Invention

5       The invention relates generally to systems  
which use and generate images during medical and surgical  
procedures, which images assist in executing the  
procedures and indicate the relative position of various  
body parts and instruments. In particular, the invention  
relates to a system for generating images during medical  
10   and surgical procedures based on a scan taken prior to or  
during the procedure and based on the present position of  
the body parts and instruments during the procedure.

      Image guided medical and surgical procedures  
comprise a technology by which scans, obtained either  
15   pre-procedurally or intra-procedurally (i.e., prior to or  
during a medical or surgical procedure), are used to  
generate images to guide a doctor during the procedure.  
The recent increase in interest in this field is a direct

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result of the recent advances in scanning technology, especially in devices using computers to generate three dimensional images of parts of the body, such as computed tomography (CT) or magnetic resonance imaging (MRI).

5       The majority of the advances in diagrammatic imaging involve devices which tend to be large, encircle the body part being imaged, and are expensive. Although the scans produced by these devices depict the body part under investigation with high resolution and good spatial  
10       fidelity, their cost usually precludes the dedication of a unit to be used during the performance of procedures. Therefore, image guided surgery is usually performed using images taken preoperatively.

15       The reliance upon preoperative images has focused image guidance largely to the cranium. The skull, by encasing the brain, serves as a rigid body which largely inhibits changes in anatomy between imaging and surgery. The skull also provides a relatively easy point of reference to which fiducials or a reference  
20       system may be attached so that registration of pre-procedural images to the procedural work space can be done simply at the beginning, during, or throughout the procedure. Registration is defined as the process of relating pre-procedural or intra-procedural scan of the  
25       anatomy undergoing surgery to the surgical or medical position of the corresponding anatomy. For example, see U.S. Patent No. 5,383,454.

30       This situation of rigid fixation and absence of anatomical movement between imaging and surgery is unique to the skull and intracranial contents and permits a simple one-to-one registration process as shown in Figure 1. The position during a medical procedure or surgery is in registration with the pre-procedural image data set  
35       because of the absence of anatomical movement from the time of the scan until the time of the procedure; in

effect, the skull and it's intracranial contents comprise a "rigid body," that is, an object which does not deform internally. In almost every other part of the body there is ample opportunity for movement within the anatomy  
5 which degrades the fidelity by which the pre-procedural scans depict the intra-procedural anatomy. Therefore, additional innovations are needed to bring image guidance to the rest of the body beyond the cranium.

The accuracy of image guided surgery relies  
10 upon the ability to generate images during medical and surgical procedures based on scans taken prior to or during the procedure and based on the present position and shape of the body parts during the procedure. Two types of body parts are addressed herein: 1) structures  
15 within the body that do not change shape, do not compress, nor deform between the process of imaging and the medical procedure, which are termed "rigid bodies," and are exemplified by the bones of the skeleton; and 2) structures within the body that can change shape and  
20 deform between the process of imaging and the medical procedure structures are termed "semi-rigid bodies," and are exemplified by the liver or prostate. Both types of body parts are likely targets for medical or surgical procedures either for repair, fusion, resection, biopsy,  
25 or radiation treatment. Therefore, a technique is needed whereby registration can be performed between the body parts as depicted pre-procedurally on scans and the position and shape of these same body parts as detected intra-procedurally. This technique must take into  
30 account that movement can occur between portions of the body which are not rigidly joined, such as bones connected by a joint, or fragments of a broken bone, and that shape deformation can occur for semi-rigid bodies, such as the liver or prostate. In particular, the  
35 technique must be able to modify the scanned image dataset such that the modified image dataset which is

used for localization and display, corresponds to position and/or shape of the body part(s) of interest during a medical or surgical procedure. A key to achieving this correspondence is the ability to precisely  
5 detect and track the position and/or shape of the body part(s) of interest during the medical or surgical procedure, as well as to track instruments, ----- or radiation used during the said procedure.

#### Summary of the Invention

10 It is an object of this invention to provide a system which allows registration between a body part depicted in pre-procedural images and tracked during surgery.

15 It is a further object of this invention to provide a system which allows registration between a semi-rigid body such as the liver depicted in pre-procedural images and detected during surgery.

20 It is a further object of this invention to provide a system which allows registration between multiple body parts such as skeletal elements depicted in pre-procedural images and detected during surgery.

25 It is a further object of this invention to provide a system which can localize a semi-rigid body that may deform between imaging and a procedure and provide a display during the procedure of the body in its deformed shape.

30 It is a further object of this invention to provide a system which can localize multiple rigid bodies that move with respect to each other between imaging and a procedure and provide a display during the procedure of the bodies in their displaced positions.

35 It is another object of this invention to provide a system for use during a medical or surgical procedure on the body, the system generating a display representing the position of one or more body elements

during the procedure based on a scan generated by a scanner either prior to or during the procedure.

5 It is another object of this invention to provide a system for use during a medical or surgical procedure on a body which modifies the scan taken prior to or during a procedure according to the identified relative position of each of the elements during the procedure.

10 It is another object of this invention to provide a system for use during a medical or surgical procedure on a body which modifies the image data set according to the identified shape of each of the element during the procedure.

15 It is another object of this invention to provide a system which generates a display representative of the position of a medical or surgical instrument in relation to the body element(s) during a procedure.

20 It is a further object of this invention to provide a system for use during image guided medical and surgical procedures which is easily employed by the doctor or surgeon conducting the procedure.

25 It is another object of this invention to provide a system which determines the relative position and/or shape of body elements during a medical or surgical procedure based on the contour of the body elements which can avoid the need for exposing the body elements.

30 It is still another object of this invention to provide a system which employs one or more two dimensional fluoroscopic or x-ray images of body elements to determine their relative position and/or shape in three dimensions.

35 It is yet a further object of this invention to describe a surgical or medical procedure which employs a display representing the position of the body element(s)

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during the procedure based on an image data set of the body element(s) generated prior to the procedure.

It is a further object of this invention to provide a system and method for medical or surgical  
5 procedures which allows repositioning of body elements during the procedure and still permits the generation of an image showing the relative position of the body elements.

It is a further object of this invention to provide a system and method for medical or surgical  
10 procedures which allows reshaping of the body element(s) during the procedure and still permits the generation of an image showing the position and current shape of the body elements.

It is a further object of this invention to  
15 provide a system which can localize a body element and provide a display during the procedure of the position of the body element relative to an instrument, such as a forceps, microscope, or laser, so that the instrument can be precisely located relative to the body element.

20 Other objects and features will be in part apparent and in part pointed out hereinafter.

The invention comprises a system for use during a procedure on a body, said system generating a display representing a position of two or more body elements during  
25 the procedure, said system comprising: a memory storing an image data set representing the position of the two or more body elements based on scans taken of the body, the image data set having a plurality of data points and corresponding to a plurality of reference points for each of the body  
30 elements, the reference points of a particular body element having a known spatial relation to the data points of the

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particular body element; means for identifying, during the procedure, the position of the reference points of each of the body elements relative to the reference points of the other body elements; a processor modifying the spatial  
5 relation of the data points of one body element relative to the data points of another body element according to the identified relative position of the reference points during the procedure as identified by the identifying means, said processor generating a displaced image data set representing  
10 the position of the body elements during the procedure; and a display utilizing the displaced image data set generated by the processor and providing a display, illustrating the relative position of the body elements during the procedure.

The invention also comprises a method for use  
15 during a procedure, said method generating a display representing a position of two or more body elements during the procedure, said method comprising the steps of: storing an image data set in a memory, the image data set representing the position of the two or more body elements  
20 based on scans taken of the body; reading the image data set stored in the memory, said image data set having a plurality of data points and a plurality of reference points for each of the body elements, the data points of each body element having a spatial relation to the data points of another body  
25 element, the reference points of a particular body element having a known spatial relation to the data points of the particular body element; identifying, during the procedure, the position of each of the reference points of each of the body elements relative to the reference points of the other  
30 body elements; modifying the spatial relation of the data points of one body element relative to the data points of another body element according to the identified relative position of the reference points during the procedure in

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order to generate a displaced image data set representing the relative position of the body elements during the procedure; and generating a display based on the displaced image data set illustrating the relative position of the  
5 body elements during the procedure.

The invention also comprises a system for use during a procedure on a body, said system generating a display representing a geometrical relationship of two or more body elements during the procedure, said system  
10 comprising: a memory for storing an image data set representing the position of the two or more body elements based on scans taken of the body, the image data set having a geometrical spatial relationship of the body elements and having a plurality of reference points on each of the body  
15 elements, the reference points of a particular body element having a known spatial relation on the particular body element; means for identifying, during the procedure, a position of each of the reference points of the body elements to be displayed; a processor modifying the  
20 geometrical relationship of the body elements as necessary according to the identified position of each of the reference points as identified by the identifying means, said processor generating a displaced image data set from the modified geometrical relationship of the body elements,  
25 said displaced image data set representing the geometrical relationship of the body elements during the procedure; and a display system utilizing the displaced image data set to generate the display.

The invention also comprises a system for use  
30 during a procedure on a body, said system generating a display representing a position of two or more body elements during the procedure, said system comprising: a memory configured to store an image data set representing the



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position of the two or more body elements based on scans taken of the body, the image data set having a plurality of data points and corresponding to a plurality of reference points for each of the body elements, the reference points of a particular body element having a known spatial relation to the data points of the particular body element; means for identifying the position of the reference points; a digitizer positioned to receive a signal output by the means for identifying, said digitizer being configured to determine a three dimensional position of the reference points for the particular body element; a processor modifying the spatial relation of the data points of one body element relative to the data points of another body element according to the identified relative position of the reference points during the procedure as determined by the digitizer, said processor generating a displaced image data set representing the position of the body elements during the procedure; and a display utilizing the displaced image data set generated by the processor, illustrating the relative position of the body elements during the procedure.

The invention also comprises a system for displaying relative positions of two or more body elements during a procedure on a body, the system comprising: a memory storing an image data set, the image data set representing the position of the body elements based on scans of the body, and having a plurality of data points correlatable to a plurality of reference points for each of the body elements, the position of reference points of a particular body element relative to the data points for that particular body element being known; a reference system for identifying, during the procedure, the position of the reference points of each of the body elements relative to the reference points of the other body elements; a processor

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modifying the relative position of the data points of one body element relative to the data points of another body element according to the identified relative position of the reference points during the procedure as identified by the reference system, the processor generating a displaced image data set representing the position of the body elements during the procedure; and a display utilizing the displaced image data set generated by the processor to display the relative position of the body elements during the procedure.

10           The invention also comprises a system for use during a medical or surgical procedure on a body, said system being adapted to generate a display from an image data set representing the position of one or more body elements during the procedure based on scans taken of the body, wherein at least some of the body elements are movable with respect to each other, each scan having a reference for each of the one or more body elements, the reference of a particular body element having a known spatial relation to the particular body element said system comprising: a

15           plurality of reference frames, at least one attached to each of the movable body elements; a localizer for identifying, during the procedure, the position of the reference for each of the body elements to be displayed; a processor for modifying the image data set according to the identified

20           position of the reference during the procedure, as identified by the localizer, said processor being adapted to generate a displaced image data set representing the position and geometry of the body elements according to the identified position of the reference frames during the

25           procedure, as identified by the localizer; and a display utilizing the displaced image data set generated by the

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processor, illustrating the position and geometry of the body elements during the procedure.

The invention also comprises a method for use during a medical or surgical procedure on a body, said method being adapted to generate a display from an image data set representing the position of one or more body elements during the procedure based on scans taken of the body, wherein at least some of the body elements are movable with respect to each other, each scan having a reference for each of the one or more body elements, the reference of a particular body element having a known spatial relation to the particular body element, wherein there is a plurality of reference frames, at least one attached to each of the movable body elements; said method comprising the steps of:

identifying, during the procedure, the position of the reference for each of the body elements to be displayed; modifying the image data set according to the identified position of the reference during the procedure, as identified by the localizer; generating a displaced image data set representing the position and geometry of the body elements according to the identified position of the reference frames during the procedure; and illustrating the position and geometry of the body elements during the procedure utilizing the displaced image data set.

In addition, the invention comprises a method for displaying the relative positions of a plurality of body elements during a procedure on a body, the method comprising: storing scan images of body elements, the scan images having a plurality of data points corresponding to a plurality of reference points for each of the body elements, the position of the reference points of a particular body element relative to the data points for that particular body element being known; identifying the position of each of the

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reference points of each of the body elements relative to the reference points of the other body elements during a procedure; modifying the relative position of the data points of one body element relative to the data points of another body element according to the identified relative position of the reference points during the procedure; generating a displaced image data set representing the position of the body elements during the procedure; and displaying the relative position of the body elements during the procedure.

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5    **Brief Description of the Drawings**

Figure 1 is an illustration of the prior art system in which rigid fixation and absence of movement between imaging and surgery permits a one-to-one registration process between the pre-surgical scan and the position in surgery.

10    Figure 2A is an illustration of operation of the invention in which the pre-procedural image data set is modified in accordance with the intra-procedural position in order to generate a displaced and/or deformed data set representative of the intra-procedural position.

15    Figure 2B is a block diagram of one preferred embodiment of a system according to the invention.

Figure 3 is an illustration of the pre-procedural alignment of three body elements during scanning.

20    Figure 4 is an illustration of the intra-procedural alignment of the three body elements of Figure 3 during surgery.

Figure 5 is an illustration of three body elements, one of which has a reference frame attached thereto, in combination with a registration probe.

25    Figure 6 is an illustration showing ultrasound registration according to the invention in which emitters are attached to the ultrasound for a virtual reference and, optionally, the patient's body for an actual reference.

30    Figure 7 is an illustration of a fluoroscopic localizer according to the invention for providing projections of an image of the body elements.

Figure 8 is an illustration of a drill guide instrument of the invention wherein the position of a drill guide relative to the body elements may be displayed.

5                Figures 9 and 10 illustrate a clamped reference frame and a wired reference frame, respectively.

Figure 11 is a schematic diagram of one preferred embodiment of a cranial surgical navigation system according to the invention.

10              Figure 11A is a top plan view of one preferred embodiment of a cranial reference arc frame according to the invention.

Figure 11B is a side plan view, partially in cross section, of one preferred embodiment of a cranial reference arc frame according to the invention.

15              Figure 11C is a wiring diagram of one preferred embodiment of a cranial reference arc frame according to the invention.

Figure 12A is a top plan view of one preferred embodiment of a spinal reference arc frame according to the invention.

20              Figure 12B is a front plan view, partially in cross section, of one preferred embodiment of a spinal reference arc frame according to the invention.

25              Figure 12C is a side plan view of one preferred embodiment of a spinal reference arc frame according to the invention.

Figure 12D is a top plan view of one preferred embodiment of a thoraco-lumbar mount according to the invention.

30              Figure 12E is a front plan view, partially in cross section, of one preferred embodiment of a thoraco-lumbar mount according to the invention.

Figure 12F is a side plan view of one preferred embodiment of a thoraco-lumbar mount according to the invention.

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Figure 12G is a wiring diagram of one preferred embodiment of a spinal reference arc frame according to the invention.

5 Figure 13A is a top plan view of one preferred embodiment of a biopsy guide localization frame according to the invention.

Figure 13B is a side plan view, partially in cross section, of one preferred embodiment of a biopsy guide localization frame according to the invention.

10 Figure 13C is a front plan view of one preferred embodiment of a biopsy guide localization frame according to the invention.

Figure 13D is a top plan view of one preferred embodiment of a drill guide localization frame according to the invention.

Figure 13E is a side plan view, partially in cross section, of one preferred embodiment of a drill guide localization frame according to the invention.

20 Figure 13F is a top plan view of one preferred embodiment of a drill yoke localization frame according to the invention.

Figure 13G is a side plan view, partially in cross section, of one preferred embodiment of a drill yoke localization frame according to the invention.

25 Figure 13H is a top plan view of one preferred embodiment of a ventriculostomy probe including an integrated localization frame according to the invention.

Figure 13I is a side plan view, partially in cross section, of one preferred embodiment of a ventriculostomy probe including an integral localization frame according to the invention.

30 Figure 13J is a wiring diagram of one preferred embodiment of a localization frame according to the invention.

35 Corresponding reference characters indicate corresponding parts throughout the drawings.

Detailed Description of the Preferred Embodiments

Referring to Fig. 2, an overview of operation of one preferred embodiment of the system according to the invention is illustrated. Prior to a particular procedure, the body elements which will be part of the procedure are scanned to determine their alignment, i.e., their pre-operative position. For example, the alignment may be such as illustrated in Fig. 3 wherein body elements 10, 20, and 30 are more or less aligned in parallel. These body elements may be bones or other rigid bodies. In Fig. 3, three-dimensional skeletal elements 10, 20, 30 are depicted in two dimensions as highly stylized vertebral bodies, with square vertebra 11, 21, 31, small rectangular pedicles 12, 22, 32, and triangular spinous processes 13, 23, 33. During imaging, scans are taken at intervals through the body parts 10, 20, 30 as represented in Fig. 3 by nine straight lines generally referred to be reference character 40. At least one scan must be obtained through each of the body elements and the scans taken together constitute a three-dimensional pre-procedural image data set.

Fig. 2B is a block diagram of the system according to the invention. A scanner interface 102 allows a processor 104 to obtain the pre-procedural image data set generated by the scanner and store the data set in pre-procedural image data set memory 106. Preferably, after imaging, processor 104 applies a discrimination process to the pre-procedural image data set so that only the body elements 10, 20, 30 remain in memory 106. If a discrimination process is employed, processor 104 may execute the discrimination process while data is being transferred from the scanner through the scanner interface 102 for storage in memory 106. Alternatively, memory 106 may be used for storing undiscriminated data and a separate memory (not shown) may be provided for storing the discriminated data. In this alternative,



processor 104 would transfer the data set from the scanner through scanner interface 102 into memory 106 and then would discriminate the data stored in memory 106 to generate a discriminated image data set which would be  
5 stored in the separate memory.

Once the body elements 10, 20, 30 are discriminated and each defined as a single rigid body, they can be repositioned by established software algorithms to form the displaced image data set. Each  
10 rigid body element, 10, 20, 30, must have at least three recognizable reference points which are visible on the pre-procedural images. These reference points must be accurately detected during the procedure. For body part 10, reference points 10A, 10B, and 10C are located on the  
15 spinous process 13; for body part 20, reference points 20A and 20C are located on the vertebra 21 and reference point 20B is located on spinous process 23; and for body part 30, reference points 30A and 30B are located on the spinous process 33 and reference point 30C is located on  
20 the vertebra 31. More than one reference point can be selected on each scan through the bone, although the maximal accuracy of registration is achieved by separating the reference points as far as possible. For example, in the case of posterior spinal surgery, it may  
25 be preferable to select reference points 10A, 10B, and 10C on the spinous process which is routinely exposed during such surgery. It is contemplated that system software may allow the manual or automated identification of these same points on the images of the body elements  
30 10, 20, 30. As Fig. 3 is a two-dimensional projection of a three-dimension process, the reference points will not be limited to a perfect sagittal plane, as depicted.

After imaging, the skeletal body elements 10, 20, 30 may move with respect to each other at the joints  
35 or fracture lines. In the procedure room, such as an operating room or a room where a medical procedure will

be performed, after positioning the patient the surgery, the body elements will assume a different geometry, such as the geometry depicted in Fig. 4.

As a result of this movement, the pre-procedural image data set stored in memory 106, consisting of the scans through the skeletal elements, does not depict the operative position of the skeletal elements, as shown in Fig. 4. However, the shape of the skeletal elements, as depicted by the scans through the element, is consistent between imaging and procedure since they are rigid bodies, as indicated by the lines 40 through each element in Fig. 4. Therefore, the image data set must be modified to depict the intraprocedural geometry of the skeletal elements. This modification is performed by identifying the location of each reference point of each skeletal element in procedure space. As diagrammatically illustrated in Fig. 2, a localizer 108 (see Figure 13, below, for more details) identifies the location and provides this information so that the pre-procedural data set may be deformed or re-positioned into the displaced data set. As a result, the displaced data set is in registration with the intra-procedural position of the elements 10, 20, 30. Once the locations of the reference points are determined by the localizer 108, processor 104, which is a part of the work station, can execute software which re-positions the images of the skeletal elements to reflect the position of the actual elements in the procedure room thus forming the displaced set and the registration between the displaced set and the intra-procedural position.

Preferably, a three-dimensional digitizer may be used as the localizer 108 to determine the position and space of the elements 10, 20, 30 during the procedure. In general, the digitizer would include a reference array 110 which receives emissions from a series of emitters. Usually, the emissions consist of

some sort of energy, such as light, sound or electromagnetic radiation. The reference array 110 is distant from the emitters which are applied to and positioned in coordination with the elements being localized, determining the position of the emitters. As is apparent, the emitters may be placed distant to the elements and the reference array 110 may be attached to the elements being localized.

Referring to Fig. 2, an alternate preferred embodiment of the system according to the invention in the case where the body elements are not rigid, but rather semi-rigid such that shape deformations may occur to the body elements is described as follows. Prior to a particular procedure, the body elements which will be part of the procedure are scanned to determine their pre-operative position and shape. For example, the alignment may be such as illustrated in Fig. 3 wherein body elements 10, 20, and 30 are more or less aligned in parallel and have a defined shape. These body elements may be soft tissue such as the prostate or other semi-rigid bodies.

After imaging, the elements 10, 20, 30 may move with respect to each other and also their shape may become deformed. In the procedure room, such as an operating room or a room where a medical procedure will be performed, after positioning the patient the surgery, the body elements may assume a different geometry, such as the geometry depicted in Fig. 4 where geometry depicts both element alignment (position) and shape.

As a result of this changed geometry, the pre-procedural image data set stored in memory 106, does not depict the operative geometry of the body elements, as shown in Fig. 4. Indeed, the shape of the body elements, as depicted by the scans through the element, may have changed between imaging and procedure since they are semi-rigid bodies. Therefore, the image data set must be

modified to depict the current geometry of the body elements. This modification is performed by identifying the location of the reference points of each body element in procedure space. As diagrammatically illustrated in  
5 Fig. 2, a localizer 108 possibly in communication with a processor 104 identifies the location of the reference points and provides this information so that the pre-procedural data set may be deformed into the displaced data set. Once the locations of the reference points are  
10 determined, processor 104, which is a part of the work station, can execute software which modifies the images of the body elements to reflect the geometry of the actual elements in the procedure room thus forming the displaced set and the registration between the displaced  
15 set and the intra-procedural position. As a result, the displaced data set is in registration with the intra-procedural geometry of the elements 10, 20, 30.

According to one preferred embodiment of the invention, a reference frame 116 is attached to one of  
20 the body elements 10 at the beginning of the procedure. Various reference frame embodiments are illustrated in more detail in Figures 11 and 12, below. Reference frame 116 is equipped with a plurality of emitters 114 which together define a three-dimensional intraprocedural  
25 coordinate system with respect to the body element 10. In conventional terms, the reference frame 116 defines the stereotactic space with respect to the body element 10. Emitters 114 communicate with sensors 112 on a reference array 110 located in the procedure room and  
30 remote from the reference frame 116 and patient. If the body of the patient is not immobilized during surgery, then multiple reference frames may be required for each body element to define a surgical space with respect to each element. The surgical space may alternatively be  
35 defined by rigid fixation of the frame emitters 114 directly (or indirectly, for example, to the skin) to the

skeletal elements 10, 20, or 30. In either case, the emitters 114 emit a signal which is received by the sensors 112. The received signal is digitized to compute position, for example, by triangulation. Through such  
5 information, the localizer 108 or a digitizer which is part of the localizer 108 can determine the exact three-dimensional position of the frame emitters 114 relative to the sensors 112. Thereby, localizer 108 or the processor 104 can exactly determine the position of the  
10 reference frame 116 relative to the array which is free to move except during localization, e.g., activation of the emitters 114 on the reference frame 116 and activation of the probe emitters 112. Emitters 114 of the reference frame 116 are energized to provide radiation to  
15 the sensors 112, which radiation is received and generates signals provided to the localizer 108 for determining the position of the frame 116 relative to the array 110.

Next, it is necessary to determine the position  
20 of the body element 10, which may be a skeletal element, to which the reference frame 116 is affixed or positioned with respect to. In particular, the position of the body element 10 relative to the reference frame 116 must be determined, thereby determining the position of the body  
25 element 10 in the surgical space defined by the reference frame 116. After exposure of the reference points 10A, 10B, 10C by surgical dissection, the reference points are touched by the tip of a registration probe 118 equipped with emitters 120. As each of the reference points 10A,  
30 10B, 10C is touched by the tip of the probe 120, the emitters are energized to communicate with the sensors 112 of reference array 110. This communication permits the localizer 108 to determine the position of the registration probe 120, thereby determining the position  
35 of the tip of the probe 120, thereby determining the position of the reference point 10A on which the tip is

positioned. By touching each of the reference points 10A, 10B, 10C on each body element 10, 20, 30 involved in the procedure, an intra-procedural geometry data is generated and stored in memory 121. This data is related to the corresponding reference points on the pre-procedural images of the same elements by processor 104 which employs software to derive a transformation which allows the determination of the exact procedural position, orientation, and shape in surgical space of each body element, and thereby modifies the pre-procedural image data set stored in memory 106 to produce a displaced image data set which is stored in memory 122. The displaced image data set in memory 122 reflects the geometry of the actual elements 10, 20, 30 during the procedure. Processor 104 displays the displaced image data set on display 124 to provide a visual depiction of the geometry of the body elements 10, 20, 30 during the procedure. This image is used during the procedure to assist in the procedure. In addition, it is contemplated that an instrument, such as a forceps, a laser, a microscope, a endoscope, or a radiation delivery system, which would be used during the procedure may be modified by the addition of emitters. This modified device when moved into the area of the body elements 10, 20, 30 would be activated so that its emitters would communicate with the reference array 110 thereby permitting localizer 108 to determine the instrument's position. As a result, processor 104 would modify display 124 to indicate the position of the instrument or the instruments focal point, such as by positioning a cursor, with respect to the body elements 10, 20, 30.

Further, it is contemplated that the addition of emitters on an instrument (effector) may be used with the system in order to create a closed-loop feedback for actively (in the case of robotics) or passively controlling or monitoring the instrument and its

position. Such a control loop allows the monitoring of certain procedures such as the delivery of radiation to the body or the use of a drill where the object of the procedure is to keep the focal point of the instrument in a safe zone, i.e. a predetermined procedural plan. Such a control loop could also control the operation of a robotically controlled instrument where the robotics could be driven (directly or indirectly) by processor 104 to control the position the position of the instrument. For example, the processor could instruct a robotic arm to control the position of a laser. The laser position could be monitored, such as by emitters on the laser. The processor would be programmed with the control parameters for the laser so that it would precisely follow a predetermined path.

Reference frame 116 allows the patient to be moved during the procedure without the need for re-registering the position of each of the body elements 10, 20, 30. It is assumed that during the procedure, the body elements are fixed relative to each other. Since the reference frame 116 is fixed (directly or indirectly) to body element 10, movement of the patient results in corresponding movement of the reference frame 116. Periodically, or after each movement of the patient, array emitters 114 may be energized to communicate with the sensors 112 of reference array 110 in order to permit localizer 108 to determine the position of the reference frame 116. Since the reference frame 116 is in a known relative position to element 110 and since we have assumed that elements 20 and 30 are in fixed relation to element 10, localizer 108 and/or processor 104 can determine the position of the elements and thereby maintain registration.

An alternative to touching the reference points A, B, C with the tip of the probe 118 would be to use a contour scanner 126a with emitters attached 126b. Such a

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device, using some form of energy such as sound or light which is emitted, reflected by the contour and sensed, would allow the extraction of a contour of the body elements 10, 20, 30, thus serving as a multitude of reference points which would allow registration to occur. The registration process is analogous to the process described for ultrasound extracted contours below.

In certain situations, markers may be used on the skin surface as reference points to allow the transformation of the pre-procedural image data set into the displaced image data set. Reciprocally, skin surface fiducials applied at the time of imaging can be used to re-position the body to match the geometry during imaging and is described below.

Localization of body elements 10, 20, 30 may be desired without intra-procedural exposure of the reference points A, B, C on those body elements. Examples wherein the spine is minimally exposed include percutaneous biopsy of the spine or discectomy, spinal fixation, endoscopy, percutaneous spinal implant insertion, percutaneous fusion, insertion of drug delivery systems, and radiation delivery. In this situation, localization of reference points on the body elements must be determined by some form of imaging which can localize through overlying soft tissue and/or discriminate surrounding tissue and structures. There are currently two imaging techniques which are available to a surgeon in the operating room or a doctor in a procedure room which satisfy the needs of being low cost and portable. Both imaging techniques, ultrasonography and radiography, can produce two-or three-dimensional images which can be employed in the fashion described herein to register a three-dimensional form such as a skeletal element.



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The coupling of a three-dimensional digitizer to a probe of an ultrasound device affords benefits in that a contour can be obtained which can be related directly to a reference system that defines three-dimensional coordinates in the procedural work space, i.e., the surgical space. In the context of the present invention, a patient is imaged prior to a procedure to generate a pre-procedural image data set which is stored in memory 106. In the procedure room, the patient's body is immobilized to stabilize the spatial relationship between the body elements 10, 20, 30. A procedural reference system, surgical space, for the body is established by attaching a reference frame 116 to one of the body elements or by otherwise attaching emitters to the patient or body elements as noted above, or by attaching emitters to a device capable of tracking one of the body elements thereby forming a known relationship with the body element. For example, this could be performed by using the percutaneous placement of a reference frame similar to the one described above, radiopaque markers screwed into the elements or by placing emitters 130 directly on the skins, as illustrated in Fig. 6, based on the assumption that the skin does not move appreciably during the procedure or in respect to the body elements.

An ultrasound probe 128 equipped with at least three emitters 130 is then placed over the body element of interest. The contour (which can be either two- or three-dimensional) of the body element is then obtained using the ultrasound probe 128. This contour can be expressed directly or indirectly in the procedural coordinates defined by the reference system (surgical space). Emitters 130 communicate with sensors 112 of reference array 110 to indicate the position of the ultrasound probe 128. An ultrasound scanner 131 which energizes probe 128 determines the contour of the body

element of interest and being scanned. This contour information is provided to processor 104 for storage in intra-procedural geometry data memory 121.

5 The intra-procedural contour stored in memory 121 is then compared by a contour matching algorithm to a corresponding contour extracted from the pre-operative image data set stored in memory 106. Alternatively, a pre-procedural contour data set may be stored in memory 134 based on a pre-procedural ultrasound scan which is  
10 input into memory 134 via scanner interface 102 prior to the procedure. This comparison process continues until a match is found for each one of the elements. Through this contour matching process, a registration is obtained between the images of each body element and the  
15 corresponding position of each element in the procedural space, thereby allowing the formation of the displaced image data set 122 used for localization and display. Note that the contours used in the matching process only have to be sufficiently identical to accomplish a precise  
20 match - the contours do not have to be the same extent of the body element.

In certain instances, the ultrasound registration noted above may not be applicable. For example, ultrasound does not penetrate bone, and the  
25 presence of overlying bone would preclude the registration of an underlying skeletal element. Further, the resolution of ultrasound declines as the depth of the tissue being imaged increases and may not be useful when the skeletal element is so deep as to preclude obtaining  
30 an accurate ultrasonically generated contour. In these circumstances, a radiological method is indicated, which utilizes the greater penetrating power of x-rays.

Pre-operative imaging occurs as usual and the skeletal elements may be discriminated from the soft  
35 tissue in the image data set as above. In particular, a CT scan of the skeletal elements 10, 20, 30 could be

taken prior to the procedure. Processor 104 may then discriminate the skeletal elements and store the pre-procedural image data set in memory 106. Next, the patient is immobilized for the procedure. A radiograph of the skeletal anatomy of interest is taken by a radiographic device equipped with emitters detectible by the digitizer. For example, a fluoroscopic localizer 136 is illustrated in Fig. 7. Localizer 136 includes a device which emits x-rays such as tube 138 and a screen 140 which is sensitive to x-rays, producing an image when x-rays pass through it. This screen is referred to as a fluoroscopic plate. Emitters 142 may be positioned on the tube 138, or on the fluoroscopic plate 140 or on both. For devices in which the tube 138 is rigidly attached to the plate 140, emitters need only be provided on either the tube or the plate. Alternatively, the reference array 110 may be attached to the tube or the plate, obviating the need for emitters on this element. By passing x-rays through the skeletal element 141 of interest, a two-dimensional image based on bone density is produced and recorded by the plate. The image produced by the fluoroscopic localizer 136 is determined by the angle of the tube 138 with respect to the plate 140 and the position of the skeletal elements therebetween and can be defined with respect to procedure coordinates (surgical space). Fluoroscopic localizer 136 includes a processor which digitizes the image on the plate 140 and provides the digitized image to processor 104 for possible processing and subsequent storage in intra-procedural geometry data memory 121. Processor 104 may simulate the generation of this two-dimensional x-ray image by creating a series of two-dimensional projection of the three-dimensional skeletal elements that have been discriminated in the image data set stored in memory 106. Each two dimensional projection would represent the passage of an X-ray beam through the body at a specific

angle and distance. In order to form the displaced data set and thus achieve registration, an iterative process is used which selects that a two-dimensional projection through the displaced data set that most closely matches the actual radiographic image(s) stored in memory 121. The described process can utilize more than one radiographic image. Since the processor 104 is also aware of the position of the fluoroscopic localizers because of the emitters 142 thereon, which are in communication with localizer 108, the exact position of the skeletal elements during the procedure is determined.

As noted above, the procedural reference system or surgical space for the body can be established by attaching emitters to a device capable of detecting and tracking, i.e. identifying, one of the body elements thereby forming a known relationship with the body element. For example, the emitters 130 on the ultrasound probe 128 together and without the three emitters on the patient's body form a type of reference frame 116 as depicted in Figure 6 which can be virtually attached to body element 10 by continuously or periodically updating the ultrasound contour of body element 10 stored in intra-procedural geometry data memory 121 which the processor 104 then uses to match to the contour of body element 10 stored in pre-procedural memory 106 thereby continuously or periodically updating the displaced image data set in memory 122 so that registration with the procedural position of the body elements is maintained. It is contemplated that a virtual reference frame can be accomplished using any number of devices that are capable of detecting and tracking a body element such as radiographic devices (fluoroscope), endoscopes, or contour scanners.

The above solutions achieve registration by the formation of a displaced image data set stored in memory 122 which matches the displacement of the skeletal

elements at the time of the procedure. An alternative technique to achieve registration is to ensure that the positions of the skeletal elements during the procedure are identical to that found at the time of imaging. This  
5 can be achieved by using a frame that adjusts and immobilizes the patient's position. In this technique, at least three markers are placed on the skin prior to imaging. These markers have to be detectible by the imaging technique employed and are called fiducials. A  
10 multiplicity of fiducials is desirable for improving accuracy.

During the procedure, the patient's body is placed on a frame that allows precise positioning. Such frames are commonly used for spinal surgery and could be  
15 modified to allow their use during imaging and could be used for repositioning the patient during the procedure. These frames could be equipped with drive mechanisms that allow the body to be moved slowly through a variety of positions. The fiducials placed at the time of imaging  
20 are replaced by emitters. By activating the drive mechanism on the frame, the exact position of the emitters can be determined during the procedure and compared to the position of the fiducials on the pre-procedural image data set stored in memory 106. Once the  
25 emitters assume a geometry identical to the geometry of the fiducials of the image data set, it is considered that the skeletal elements will have resumed a geometric relationship identical to the position during the pre-procedural scan, and the procedure can be performed using  
30 the unaltered image data set stored in memory 106.

In general, instrumentation employed during procedures on the skeleton is somewhat different than that used for cranial applications. Rather than being concerned with the current location, surgery on the  
35 skeleton usually consists of placing hardware through bones, taking a biopsy through the bone, or removing

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fragments. Therefore, the instrumentation has to be specialized for this application.

One instrument that is used commonly is a drill. By placing emitters on a surgical drill, and by having a fixed relationship between the drill body and its tip (usually a drill bit), the direction and position of the drill bit can be determined. At least three emitters would be needed on the drill, as most drills have a complex three-dimensional shape. Alternatively, emitters could be placed on a drill guide tube 800 having emitters 802, and the direction 804 of the screw being placed or hole being made could be determined by the digitizer and indicated on the image data set (see Fig. 8). The skeletal element 806 would also have emitters thereon to indicate its position.

Besides modification of existing instrumentation, new instrumentation is required to provide a reference system for surgery as discussed above. These reference frames, each equipped with at least 3 emitters, require fixation to the bone which prevents movement or rotation.

For open surgery, a clamp like arrangement, as depicted in Fig. 9, can be used. A clamp 900 is equipped with at least two points 902, 904, 906, 908 which provide fixation to a projection 910 of a skeletal element. By using at least two point fixation the clamp 900, which functions as a reference frame, will not rotate with respect to the skeletal element. The clamp includes emitters 912, 914, 916 which communicate with the array to indicate the position of the skeletal element as it is moved during the procedure.

Many procedures deal with bone fragments 940 which are not exposed during surgery, but simply fixated with either wires or screws 950, 952 introduced through the skin 954. Fig. 10 depicts a reference platform 956 attached to such wires or screws 950, 952 projecting

through the skin 954. The platform 956 includes a plurality of emitters 958, 960, 962, 964 which communicate with the array to indicate the position of the bone fragment 940 as it is moved during the  
5 procedure.

The reference frame can be slipped over or attached to the projecting screws or wires to establish a reference system. Alternatively, the frame can be attached to only one wire, as long as the method of  
10 attachment of the frame to the screw or wire prevents rotation, and that the wire or screw cannot rotate within the attached skeletal element.

#### REFERENCE AND LOCALIZATION FRAMES

15 Fig. 11 is a schematic diagram of one preferred embodiment of a cranial surgical navigation system according to the invention. Portable system cabinet 102 includes a surgical work station 104 which is supported for viewing by the surgeon or technician using the  
20 system. Work station 104 includes a screen 106 for illustrating the various scans and is connected to a personal computer 108 for controlling the monitor 106. The system also includes an optical digitizer including a camera array 110, a camera mounting stand 112 for  
25 supporting the array remote from and in line of sight with the patient, a digitizer control unit 114 on the portable system cabinet 102 and connected to the computer 108, a foot switch 116 for controlling operation of the system and a breakout box 118 for interconnecting the  
30 foot switch 116 and the digitizer control unit 114.

Also connected via the break out box 118 is a reference frame assembly 120 including a reference frame 122 with cable connected to the break out box 118, a vertical support assembly 124, a head clamp attachment  
35 126 and a horizontal support assembly 128. Optical probe 130 (which is a localization frame) is also connected via

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cable to the digitizer control unit 114 via the break out box 118.

In operation, a patient's head (or other "rigid" body element) is affixed to the head clamp attachment 126. To determine the position of optical probe 130 with respect to the head within the head clamp attachment 126, a surgeon would step on pedal 116 to energize the emitters of reference frame 122. The emitters would generate a light signal which would be picked up by camera array 110 and triangulated to determine the position of the head. The emitters of the optical probe 164 would also be energized to emit light signals which are picked up by the camera array to determine the position of the optical probe 164. Based on the relative position of the head and the probe 164, control box 114 would illustrate a preoperative scan on the screen of monitor 106 which would indicate the position of the probe relative to and/or within the head.

Fig. 11A is a top plan view of one preferred embodiment of a cranial reference arc frame 122 according to the invention. Reference frame 122 is for use with a surgical navigation system such as illustrated in Fig. 11 having a sensor array such as camera array 110 which is in communication with the reference frame 122 to identify its position. The reference frame 122 includes a base member 132 having an upper base 134 and a base plate 136 which each have a semi-circular configuration and are joined together by screws 138 to form a cavity 140 therebetween. The base and plate may be made of anodized aluminum or other autoclavable material. The top of the upper base may be provided with one or more spring clamps 142 for engaging a Leyla retractor arm. As shown in Fig. 11A, the upper base is provided with five spring clamps 142.

Either or both ends of the reference frame 122 may be provided with a bayonet fitting 144 for engaging a



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clamp which would also engage a Leyla retractor. One or both ends of the reference frame 122 is also formed into a radial projection 146 for supporting a screw 148 and crank handle 150 used to lock the reference frame to a head clamp such as head clamp 126 shown in Fig. 11 or a Mayfield Triad™ surgical clamp. This allows the reference frame 122 to be placed in a fixed position relative to the head so that any movement of the head would also include corresponding movement of the reference frame 122.

Radial projection 146, screw 148 and handle 150 constitute a coupling on the base member 132 for engaging a structure attached to a body part (the head) thereby providing a fixed reference relative to the head in order to maintain the base member 132 in fixed relation to the head.

Equally spaced about the reference frame 122 are a plurality of LEDs 152 for communicating with the camera array 110. The LEDs 152 are mounted in holes 154 in the upper base 134, which holes 154 are in communication with the cavity 140. Wires 156 are connected to each of the terminals of the LEDs 152 are positioned within the cavity 140. The other ends of the wires are connected to a connector 158 for engaging a cable connected to the digitizer 114 of the surgical navigation system. The cable provides signals for activating the LEDs 152. Connector 158 is mounted on a support projection 160 which projects from the base plate 136. This support projection 160 has a channel therein for permitting the wires to be connected to the connector 128. Fig. 11A is a wiring diagram of one preferred embodiment of the reference frame 122 according to the invention. As is illustrated in Fig. 11C, each LED terminal is connected to a separate pin of the connector 158. Although the invention is illustrated as having a connector for engaging a cable, it is contemplated that

the reference frame 122 may be battery operated so that no cable is necessary.

The reference frame 122 is essentially a semi-circular arc so that it fits around the head of the patient to allow communication of multiple LEDs 152 on the reference frame 122 with the camera array 110. The multiple LEDs 152 on the reference frame 122 are positioned in a precisely known geometric arrangement so that the calibration of the camera array 110 can be checked continuously by comparing the LEDs geometric positions as calculated by the digitizer 114 with those precisely known geometric positions. Inconsistencies in this information indicates the need to recalibrate the system or to reposition the reference frame 122 so that it can more accurately communicate with the camera array 110. Frame 122 also includes a calibration divot 162. In particular, divot 162 is an exactly located depression within the upper base 134 and is used to calibrate or check the calibration during the medical or surgical procedure the position of the tip of the probe. The precise location of each of the LEDs 152 relative to the calibration divot 162 is known. Therefore, locating a tip of a localization frame probe in the calibration divot 162 allows the calibration or the calibration check of the probes in the following manner. The tip of the probe is located within the calibration divot 162 and the LEDs on the probe are energized to provide light signals to the camera array 110. The LEDs on the reference frame 122 are also energized to communicate with the camera array 110. Using the known position of the divot 162 with respect to the position of each of the LEDs 152 as calculated by the digitizer 114, the location of the calibration divot 162 is compared to the location of the tip of the probe as calculated by the digitizer using the LEDs on the probe in order to confirm that there is no distortion in the probe tip relative to the divot 162.

Distortion in the probe tip indicates the need to recalibrate the probe so that it can more accurately communicate with the camera array 110 or to retire the probe.

5 Figs. 12A, 12B, and 12C illustrate another preferred embodiment of the reference frame in the form of a spine reference arc frame 200. As with reference frame 122, spine reference arc frame 200 has an upper base 202 which engages a base plate 204 to form a cavity 10 206 therebetween. As shown in Fig. 12A, the spine reference arc frame 200 has a generally U-shape configuration with LEDs 208 located at the ends of the legs 209 of the U-shaped member and at the intersection of the legs and base 211 of the U-shaped member. 15 Projecting laterally from the base 211 is a coupling 210 for engaging a thoraco-lumbar mount 212 as illustrated in Figs. 12D, 12E, and 12F. Also positioned on the base 211 is a calibration divot 214 which is a depression having the same purpose as the calibration divot 162 of the 20 reference frame 122. Coupling 210 has twenty-four evenly spaced teeth 216 arranged in a circular pattern for engaging the twenty-four equally spaced teeth 218 of the thoraco-lumbar mount. This allows the spine reference arc frame 200 to be positioned to form various angles 25 relative to the mount 212. It is contemplated that any other variable position connector may be used to join the spine reference arc frame 200 and the mount 212. Base plate 204 has an opening therein for engaging a connector 220 for receiving a cable to the digitizer control unit 30 114. The LEDs 208 are connected to the connector 220 by wires 222 as illustrated in wiring diagram Fig. 12G.

Referring to Figs. 12D, 12E, and 12F, thoraco-lumbar mount 212 comprises a clamp shaft 224 having an axial bore therein within which is positioned an 35 actuating shaft 226 which is connected to an actuating knob 228 extending beyond the end of clamp shaft 224.

The end of the actuating shaft 226 opposite the actuating knob 228 has an internal threaded bore 230 which engages external threads of an actuation screw 232. A U-shaped head 234 of screw 232 supports a pivot pin 236 between  
5 its legs. The pivot pin passes through the jaws 238 so that the jaws 238 rotate about the pivot pin 236 and move relative to each other defining a receiving area 240 within which a spinal bone or other body part may be clamped. The jaws 238 have teeth 239 for engaging a  
10 spinal bone or other body part and are spring loaded and held in their open position by spring plungers 242. As the actuating knob 228 is turned to engage the threads of actuation screw 232, the screw 232 is drawn into the bore 230 also drawing the jaws into a housing 246. This  
15 results in the camming surfaces 244 of housing 246 engaging the follower surfaces 248 of the jaws 238 closing the jaws and closing the receiving area 240 as the jaws are pulled into the housing.

The other end of clamp shaft 224 has a  
20 perpendicular projection 250 for supporting the teeth 218 which engage the teeth 216 of the coupling 210 of the spine reference arc frame 200. A spine reference arc clamp screw 252 passes through the array of teeth 218 and engages a threaded opening 254 in the coupling 210 of  
25 frame 200. Screw 252 engages opening 254 and locks teeth 216 and teeth 218 together to fix the angle between the spine reference arc frame 200 and the thoraco-lumbar mount 212. As a result, when the mount 212 is connected to a bone by placing the bone in the receiving area 240  
30 and turning the actuating knob 228 to close the jaws 238 and the receiving area, the frame 200 is in a fixed position relative to the bone which is engaged by the jaws. Any movement of the bone results in movement of the frame 200 which can be detected by the camera array  
35 110.

Referring to Figs. 13A, 13B and 13C, one preferred embodiment of a localization biopsy guide frame 300 is illustrated. In general, the frame 300 includes a localization frame 302 which supports a biopsy guide 304 and which also supports a support pin 306. The localization frame 302 is comprised of an upper base 308 and a base plate 310 which join to form a cavity 312 within which the wires 314 connecting to the LEDs 316 are located. As shown in the figure 13A, the localization frame has an elongated portion 318 and a generally V-shaped portion 320 having legs 322 and 324. An LED 316 is located at the end of each of the legs 322 and an LED 316 is also located at the ends of the elongated portion 318. As a result the four LEDs 316 form a rectangular array. However, the underlying localization frame 302 does not have a rectangular configuration which allows it to be adapted for other uses, such as a drill guide assembly as illustrated and described below with regard to Figs. 13D and 13E. In general, the V-shaped portion 320 extends laterally from the elongated portion 318 in order to accomplish the rectangular configuration of the LEDs 316. Note that a rectangular configuration for the LEDs 316 is not required and that in fact, a trapezoidal configuration for the LEDs 316 may be preferred in order to uniquely distinguish the orientation of the localization frame 302. Support pin 306 passes through the upper base 308 and is essentially parallel to a linear axis defined by the elongated portion 318. The purpose of support pin 306 is to allow clamps to engage it so that the localization biopsy guide frame 300 can be placed in a particular position relative to a body part in order to guide a biopsy needle.

In order to guide a biopsy needle, the localization frame 302 is fitted with a biopsy guide 304 which is mounted to the top of the upper base 308 and held in place by a clamp 328 which engages

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the upper base 308 via four screws 330. The upper base 308 is also provided with a semicircular channel 332 which forms a seat for receiving the biopsy guide 326. The guide 304 comprises a hollow tube 334 having a collar 336 at one end thereof, which has a threaded radial opening for receiving set screw 338.

The base plate 310 is fitted with a connector 340 for engaging a cable which is connected to the digitizer 114 for providing signals for energizing the LEDs 316. Figure 12G illustrates one preferred embodiment of a wiring diagram which interconnects the connector 340 and four LEDs.

The localization frame 302 is made of the same material as the reference frame 122, i.e., ULTEM<sup>TM</sup> 1000 black which is autoclavable. The biopsy guide 304 may be stainless steel or any other autoclavable metal or plastic material. As with the reference frame, the localization frame may be battery operated thereby avoiding the need for a cable or a connector for engaging the cable.

Figs. 13D and 13E illustrate another localization device in the form of a localization drill guide assembly 350. The assembly 350 includes a localization frame 302 which is the same as the frame used for the localization biopsy guide frame 300, except that it does not have a support pin 306. It does have a semicircular channel 332 in the upper base 308 which receives a handle and drill guide assembly 354 instead of the biopsy guide tube assembly 304. Assembly 354 includes a handle 356 which is used by the surgeon, doctor, technician or nurse conducting the procedure. Handle 356 has a bore 358 therein for receiving a shaft 360 which is seated within the semicircular channel 332. The shaft terminates into an integral collar 362 which supports a drill guide tube 364. The axis of the drill

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guide tube 364 is at an angle relative to the axis of the shaft 360 to assist in aligning the drill guide tube 364 relative to the point at which the drill bit will be entering the patient's body. In one preferred embodiment, handle and drill guide assembly 354 is a standard off-the-shelf instrument which is mounted to the channel 332 of the localization frame 302. The handle and drill guide assembly 354 may be a Sofamor Danek Part 870-705. Screws 366 (having heads insulated with high temperature RTV compound) attach the shaft 360 to the upper base 308 of the localization frame 302 and hold the shaft 360 in place within the channel 332. As noted above, the V-shaped portion 320 of the localization frame 302 forms an opening 368 between its legs 322 and 324 so that the drill guide tube 364 may be located therebetween and project downwardly from the plane generally defined by the localization frame 302. This allows the surgeon to sight in the position of the drill guide tube 364 by looking through the tube. Connector 370 is similar to connector 340, except that it provides an angular engagement with the cable which allows for more freedom of movement of the localization drill guide assembly 350. As with the localization frame noted above, the frame itself is made of ULTEM 1000 which is autoclavable. The handle may be wood, plastic, or any other autoclavable material and the shaft, collar and drill guide may be metal, plastic or other autoclavable material, such as stainless steel. Figure 13J illustrates a preferred embodiment of the wiring diagram for the localization drill guide assembly 350.

Figs. 13F and 13G illustrate another localization device in the form of a drill yoke localization frame 400. This frame 400 includes a localization frame 302 of the same configuration as the localization frames for the localization biopsy guide frame 300 and the localization drill guide assembly 350.

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Projecting from the underside of the base plate 310 is a support member 402 which also supports a drill yoke 404 in a plane which is essentially perpendicular to the plane defined by the localization frame 302. Yoke 404 is essentially a collar which fits over the housing of a Midas Rex™ drill and is fixedly attached thereto by a set screw 406. The drill yoke localization frame 400 allows the drill housing to be precisely positioned for use during surgery.

Support member 402 also supports a connector 408 for receiving a cable which is connected to the digitizer control unit 114. Support member 402 has a hollow channel therein so that the connector 408 may be connected to the wires 410 which connect to the LEDs 316. Figure 13J illustrates one preferred embodiment of a wiring connection between the LEDs 316 and the connector 408.

Figs. 13H and 13I illustrate another localization device in the form of a ventriculostomy probe 500. Probe 500 includes a handle 502 having a bore 504 therein for receiving a support shaft 506 which in turn supports a catheter guide tube 508 along an axis which is parallel to the axis of the handle 502. The handle includes three LEDs 510 mounted along its top surface for communication with the camera array 110. The handle 502 has a hollow channel terminating in a bore 512 for receiving a connector 514. The connector 514 is connected to wires 516 which are also connected to the terminals of the LEDs 510. Figure 13J illustrates one preferred embodiment of a wiring diagram for interconnecting the connector 514 and the LEDs 510. In operation, the tube 508 is positioned within the body, the brain for example, so that a catheter may be inserted within the body. Tube 508 includes a top slot 518 which allows a catheter to be inserted therein. Preferably, the tube tip at its center is collinear with the chip



height of all three LEDs 510 so that a linear axis is defined therebetween. Based on this linear axis and the predetermined knowledge of the distance between the tip and the LEDs 510, the camera array 110 and digitizer 114  
5 can determine the position of the tip at any instant during a surgical or medical procedure.

The system of the invention may be used in the following manner. A reference frame is attached to a body part. For example, cranial reference arc frame 122  
10 may be attached directly to a head via a head clamp such as a Mayfield clamp or spine reference arc frame 200 may be attached directly to a spinous bone via thoraco-lumbar mount 212. Thereafter, movement of the body part will result in corresponding movement of the attached  
15 reference frame. The position of the body part may be tracked by energizing the LEDs of the reference frame to provide a signal to the camera array 110 so that the array can determine and track the position of the reference frame and, consequently, the position of the  
20 body part.

A localization frame is used to precisely position an instrument relative to the body part. For example, a localization biopsy guide frame 300 may be used to position a biopsy needle relative to the body  
25 part. Alternatively, a localization drill guide assembly 350 may be used to position a drill bit relative to the body part. Alternatively, a drill yoke localization frame 400 may be used to position a drill relative to the body part. Alternatively, a ventriculostomy probe 500  
30 may be used to position a catheter relative to a body part. The position of the instrument may be tracked by energizing the LEDs of the localization frame to provide a signal to the camera array 110 so that the array can determine and track the position of the localization  
35 frame and, consequently, the position of the instrument.

During calibration of the system, the position of the reference frame relative to the body part is determined. Markers used during the preoperative scan are located and identified in coordinates of the surgical space as defined by the reference frame. Note that anatomic landmarks may be used as markers. This provides a relationship between the preoperative scan space and the surgical space. Once this relationship is established, the system knows the position of the preoperative scans relative to the reference frame and thus can generate scans which illustrate the position of the localization frame and the instrument relative to the body part. In other words, the system accomplishes image guided surgery. The system is ideally suited for locating small, deep-seated vascular lesions and tumors and for reducing the extent of the microsurgical dissection. It is also useful in identifying boundaries. For example, suppose a surgeon is trying to identify a boundary between normal brain and large supratentorial gliomas, which may be clearly shown on the preoperative scans but which may be difficult to visually locate in the operating room during a procedure. The surgeon would take a localization probe and position it a point near the boundary. The LEDs of the reference frame and localization probe are fired by use of the foot switch 116. As a result, the monitor 106 would provide a screen showing the position of the probe relative to a preoperative scan. By referring to the monitor, the surgeon can now determine the direction in which the probe should be more to more precisely locate the boundary. Once the boundary is located, microcottonoid markers can be placed at the boundary of the tumor as displayed on the monitor before resection is started. The placement of ventricular catheters for shunts, ventriculostomy, or reservoirs is also facilitated by the use of the system, especially in patients who have small

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ventricles or who have underlying coagulopathy (e.g., liver failure, acquired immunodeficiency syndrome) that makes a single pass desirable. The system can also be useful for performing stereotactic biopsies. For further  
5 information regarding the system, see the following articles:

Germano, Isabelle M., The NeuroStation System for Image-Guided, Frameless Stereotaxy, Neurosurgery, Vol. 37, No.  
10 2, August 1995.

Smith et al., The Neurostation™-A Highly accurate, Minimally Invasive Solution to Frameless Stereotactic Neurosurgery, Computerized Medical Imaging and Graphics, Vol. 18, No. 4, pp. 247-256, 1994.

15 In view of the above, it will be seen that the several objects of the invention are achieved and other advantageous results attained.

As various changes could be made in the above constructions, products, and methods without departing  
20 from the scope of the invention, it is intended that all matter contained in the above description and shown in the accompanying drawings shall be interpreted as illustrative and not in a limiting sense.

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CLAIMS:

1. A system for use during a procedure on a body,  
said system generating a display representing a position of  
two or more body elements during the procedure, said system  
5 comprising:

a memory storing an image data set representing  
the position of the two or more body elements based on scans  
taken of the body, the image data set having a plurality of  
data points and corresponding to a plurality of reference  
10 points for each of the body elements, the reference points  
of a particular body element having a known spatial relation  
to the data points of the particular body element;

means for identifying, during the procedure, the  
position of the reference points of each of the body  
15 elements relative to the reference points of the other body  
elements;

a processor modifying the spatial relation of the  
data points of one body element relative to the data points  
of another body element according to the identified relative  
20 position of the reference points during the procedure as  
identified by the identifying means, said processor  
generating a displaced image data set representing the  
position of the body elements during the procedure; and

a display utilizing the displaced image data set  
25 generated by the processor and providing a display  
illustrating the relative position of the body elements  
during the procedure.

2. The system of claim 1 wherein the reference points  
are defined in relation to the body elements and further  
30 comprising:

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a medical or surgical instrument;

means for identifying, during the procedure, the position of medical or surgical instrument relative to one or more of the body elements; and

5            wherein the display is responsive to the medical or surgical instrument position identifying means and provides a display to illustrate during the procedure the relative position of the body elements relative to the medical or surgical instrument.

10        3.            The system of claim 2 wherein the medical or surgical instrument position identifying means determines an orientation of the medical or surgical instrument relative to the body elements and wherein the display illustrates the orientation of the medical or surgical instrument relative  
15 to the body elements.

4.            The system of claim 1 wherein the identifying means comprises:

a reference array having a location for providing a reference; and

20            means for determining the position of the reference points of the body elements to be displayed relative to the reference array.

5.            The system of claim 4 further comprising a registration probe in communication with the reference array  
25 and wherein the determining means determines the position of a tip of the registration probe relative to the reference array whereby the position of the reference points of the body elements can be determined by positioning the tip of the registration probe at each of the reference points.

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6. The system of claim 5 wherein the reference array includes sensors and wherein the registration probe includes emitters communicating with the sensors of the reference array to indicate the position of the registration probe relative to the reference array.

7. The system of claim 5 wherein the registration probe includes sensors and wherein the reference array includes emitters communicating with the sensors of the registration probe to indicate the position of the registration probe relative to the reference array.

8. The system of claim 4 further comprising a reference frame having a position in known relation to one of the body elements, said reference frame in communication with the reference array, and further comprising means for determining the position of the reference frame relative to the reference array; whereby the body may be moved during the procedure so that the system can determine the position of each of the body elements after movement without again identifying the relative position of each of the reference points of each of the body elements.

9. The system of claim 8 wherein the reference array includes sensors and wherein the reference frame is attached to one of the body elements and includes emitters communicating with the sensors of the reference array to indicate the position of the reference frame relative to the reference array.

10. The system of claim 8 wherein the reference frame includes sensors and wherein the reference array is adapted to be attached to one of the body elements and includes emitters communicating with the sensors of the reference

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frame to indicate the position of the reference frame relative to the reference array.

11. The system of claim 1 further comprising means for discriminating the body elements of the image data set by  
5 creating an image data subset defining each of the body elements.

12. The system of claim 11 wherein the processor translates each of the image data subsets from the position of the body elements at a prior point in time to the  
10 position of the body elements during the procedure whereby the displaced data set consists of the translated image data subsets.

13. The system of claim 11 wherein the identifying means comprises a device configured to determine a position  
15 of a contour of each of the body elements during the procedure and wherein the processor compares the position of the contour of each of the body elements at a point in time during the procedure as determined by the device to the position of the contour of each of the body elements prior  
20 to the point in time as represented by the image data subset.

14. The system of claim 13 wherein the identifying means comprises an ultrasound probe for determining a position of a contour of each of the body elements during  
25 the procedure and wherein the processor compares the position of the contour of the each of the body elements at a point in time during the procedure as determined by the device to the position of the contour of each of the body elements prior to the point in time as represented by the  
30 image data subset whereby, the contour of the body elements may be determined without the need for exposing the body elements.

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15. The system of claim 13 wherein the identifying means comprises a scanner for determining a position of a contour of each of the body elements during the procedure and wherein the processor compares the position of the contour of each of the body elements at a point in time during the procedure as determined by the device to the position of the contour of each of the body elements prior to the point in time as represented by the image data subset.

10 16. The system of claim 14 further comprising a reference array and wherein said ultrasound probe has emitters thereon in communication with the reference array and wherein the determining means is adapted to determine the position of the ultrasound probe relative to the reference array whereby the position of the contour of each body element can be determined.

17. The system of claim 14 comprising a reference array having emitters thereon in communication with the ultrasound probe and wherein the determining means is adapted to determine the position of the ultrasound probe relative to the reference array whereby the position of the contour of each body element can be determined.

18. The system of claim 15 further comprising a reference array and wherein said scanner has emitters thereon in communication with the reference array and wherein the determining means is adapted to determine the position of the scanner relative to the reference array whereby the position of the contour of each body element can be determined.

19. The system of claim 15 comprising a reference array having emitters thereon in communication with the scanner and wherein the determining means is adapted to



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determine the position of the scanner relative to the reference array whereby the position of the contour of each body element can be determined.

20. The system of claim 4 further comprising a  
5 fluoroscopic device for determining a position of a projection of each of the body elements during the procedure and wherein the processor compares the position of the projection of each of the body elements at a point in time during the procedure to the position of the projection of  
10 each of the body elements prior to the point in time.

21. The system of claim 20 wherein the fluoroscopic device comprises a fluoroscopic tube in fixed relation to a fluoroscopic plate between which the body elements are located for determining a position of a projection of each  
15 of the body elements during the procedure and wherein the processor compares the position of the projection of each of the body elements at a point in time during the procedure to the position of the projection of each of the body elements prior to the point in time.

20 22. The system of claim 21 further comprising a reference array and wherein said fluoroscopic tube or said fluoroscopic plate each have emitters thereon in communication with the reference array and wherein the determining means is adapted to determine the position of  
25 the tube and plate relative to the reference array whereby the position of the projection of each body element can be determined.

23. The system of claim 21 comprising a reference array having emitters thereon in communication with the  
30 fluoroscopic tube or the fluoroscopic plate and wherein the determining means is adapted to determine the position of the tube or plate relative to the reference array whereby

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the position of the projection of each body element can be determined.

24. The system of claim 20 wherein the fluoroscopic device determines a position of a projection of each of the body elements during the procedure, and the processor compares the position of the projection of each of the body elements at a point in time during the procedure as determined by the fluoroscopic device to the position of the projection of each of the body elements prior to the point in time as represented by the image data set whereby the projection of the body elements may be determined without the need for exposing the body elements.

25. The system of claim 24 wherein the reference array has emitters or sensors thereon in communication with the fluoroscopic device and wherein the determining means determines the position of the fluoroscopic device relative to the reference array whereby the position of the projection of each body element can be determined.

26. A system according to claim 2, wherein the processor monitors the position of the instrument and deactivates it when the monitored position indicates that it is outside a predefined safe zone.

27. A system according to claim 2, further comprising robotics to control the position of the instrument and wherein the processor monitors the position of the instrument and instructs the robotics to control it in a predetermined manner.

28. A system according to claim 2 wherein the means for identifying includes emitters for emitting light, sound or electromagnetic radiation and sensors for sensing the emitted light, sound or electromagnetic radiation.

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29. A method for use during a procedure, said method generating a display representing a position of two or more body elements during the procedure, said method comprising the steps of:

5 storing an image data set in a memory, the image data set representing the position of the two or more body elements based on scans taken of the body;

reading the image data set stored in the memory, said image data set having a plurality of data points and a plurality of reference points for each of the body elements,  
10 the data points of each body element having a spatial relation to the data points of another body element, the reference points of a particular body element having a known spatial relation to the data points of the particular body  
15 element;

identifying, during the procedure, the position of each of the reference points of each of the body elements relative to the reference points of the other body elements;

modifying the spatial relation of the data points  
20 of one body element relative to the data points of another body element according to the identified relative position of the reference points during the procedure in order to generate a displaced image data set representing the relative position of the body elements during the procedure;  
25 and

generating a display based on the displaced image data set illustrating the relative position of the body elements during the procedure.

30. The method of claim 29 further comprising the step  
30 of repositioning the body elements so that the display based

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on the displaced data set representing the position of the body elements at a point in time during the procedure is substantially the same as the display based on the image data set generated prior to the point in time whereby the position of the body elements after repositioning is substantially the same as the position of the body elements when the image data set was generated.

31. The method of claim 29 wherein the reference points are part of the body elements and further comprising the steps of:

providing a medical or surgical instrument;

identifying, during the procedure, the position of medical or surgical instrument relative to one or more of the body elements; and

generating a display based on the position of the medical or surgical instrument illustrating the relative position of the body elements and the medical or surgical instrument during the procedure.

32. The method of claim 31 further comprising the steps of

determining an orientation of the medical or surgical instrument relative to the body elements and

generating a display illustrating the orientation of the medical or surgical instrument relative to the body elements.

33. The method of claim 29 further comprising the steps of:

providing a reference array having a location for providing a reference; and

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determining the position of the reference points of the body elements to be displayed relative to the reference array.

34. The method of claim 33 further comprising the  
5 steps of

providing a registration probe in communication with the reference array and

determining the position of the reference points of the body elements by positioning the tip of the  
10 registration probe at each of the reference points.

35. The method of claim 33 further comprising the steps of

providing a reference frame having a position in known relation to one of the body elements, said reference  
15 frame in communication with the reference array, and;

determining the position of the reference frame relative to the reference array whereby the body may be moved during the procedure so that the method can determine the position of each of the body elements after movement  
20 without again identifying the relative position of each of the reference points of each of the body elements.

36. The method of claim 29 further comprising the step of discriminating the body elements of the image data set by creating an image data subset defining each of the body  
25 elements.

37. The method of claim 36 further comprising the step of translating each of the image data subsets from the position of the body elements at a prior point in time to the position of the body elements during the procedure

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whereby the displaced data set comprises the translated image data subsets.

38. The method of claim 36 comprising the steps of  
determining a position of a contour of each of the  
5 body elements during the procedure and

comparing the position of the contour of each of  
the body elements at a point in time during the procedure to  
the position of the contour of each of the body elements  
prior to the point in time as represented by the image data  
10 set.

39. The method of claim 29 wherein the identifying  
step comprises the steps of  
positioning the body elements between a  
fluoroscopic tube and a fluoroscope plate in fixed relation  
15 to the tube,

energizing the tube to generate a projection of  
each of the elements on the plate, determining the relative  
position of the fluoroscopic projection of each of the body  
elements during the procedure and  
20 comparing the position represented by the  
fluoroscopic projection of each of the body elements at a  
point in time during the procedure to the relative position  
of the body elements prior to the point in time.

40. A system for use during a procedure on a body,  
25 said system generating a display representing a geometrical  
relationship of two or more body elements during the  
procedure, said system comprising:

a memory for storing an image data set  
representing the position of the two or more body elements

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based on scans taken of the body, the image data set having a geometrical spatial relationship of the body elements and having a plurality of reference points on each of the body elements, the reference points of a particular body element  
5 having a known spatial relation on the particular body element;

means for identifying, during the procedure, a position of each of the reference points of the body elements to be displayed;

10 a processor modifying the geometrical relationship of the body elements as necessary according to the identified position of each of the reference points as identified by the identifying means, said processor generating a displaced image data set from the modified  
15 geometrical relationship of the body elements, said displaced image data set representing the geometrical relationship of the body elements during the procedure; and

a display system utilizing the displaced image data set to generate the display.

20 41. A system for use during a procedure on a body, said system generating a display representing a position of two or more body elements during the procedure, said system comprising:

a memory configured to store an image data set  
25 representing the position of the two or more body elements based on scans taken of the body, the image data set having a plurality of data points and corresponding to a plurality of reference points for each of the body elements, the reference points of a particular body element having a known  
30 spatial relation to the data points of the particular body element;

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means for identifying the position of the reference points;

a digitizer positioned to receive a signal output by the means for identifying, said digitizer being  
5 configured to determine a three dimensional position of the reference points for the particular body element;

a processor modifying the spatial relation of the data points of one body element relative to the data points of another body element according to the identified relative  
10 position of the reference points during the procedure as determined by the digitizer, said processor generating a displaced image data set representing the position of the body elements during the procedure; and

a display utilizing the displaced image data set  
15 generated by the processor, illustrating the relative position of the body elements during the procedure.

42. The system of claim 41 wherein the means for identifying comprises at least three light emitters positioned with respect to the reference points on the  
20 particular body element; and

light sensors positioned to detect light emitted by the at least three light emitters; and wherein the digitizer positioned to receive a signal output by the light sensors, said digitizer being configured to determine a  
25 three dimensional position of the reference points for the particular body element relative to the light emitters for the other body elements.

43. The system of claim 41 wherein the reference points are in relation to the body elements and further  
30 comprising:



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a medical or surgical instrument;

means for identifying, during the procedure, the position of the medical or surgical instrument relative to one or more of the body elements; and

5            wherein the display is responsive to the medical or surgical instrument position identifying means and includes means for illustrating, during the procedure, the relative position of the body elements relative to the medical or surgical instrument.

10    44.            A system according to claim 43, wherein the processor monitors the position of the instrument and deactivates it when the monitored position indicates that it is outside a predefined safe zone.

15    45.            A system according to claim 43, further comprising robotics to control the position of the instrument and wherein the processor monitors the position of the instrument and instructs the robotics to control it in a predetermined manner.

20    46.            A system according to claim 41 wherein the means for identifying includes emitters for emitting light, sound or electromagnetic radiation and sensors for sensing the emitted light, sound or electromagnetic radiation.

25    47.            The system of claim 43 wherein the medical or surgical instrument position identifying means determines an orientation of the medical or surgical instrument relative to the body elements and wherein the display illustrates the orientation of the medical or surgical instrument relative to the body elements.

30    48.            The system of claim 41 further comprising means for discriminating the body elements of the image data set

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by creating an image data subset defining each of the body elements.

49. The system of claim 48 wherein the processor translates each of the image data subsets from the position  
5 of the body elements at a prior point in time to the position of the body elements during the procedure whereby the displaced data set consists of the translated image data subsets.

50. The system of claim 48 further comprising a  
10 contour position determining means for determining a position of a contour of each of the body elements during the procedure and wherein the processor compares the position of the contour of each of the body elements at a point in time during the procedure as determined by the  
15 contour position determining means to the position of the contour of each of the body elements prior to the point in time as represented by the image data subset.

51. The system of claim 50 wherein the contour position determining means comprises  
20 an ultrasound probe for determining a position of a contour of each of the body elements during the procedure and

wherein the processor compares the position of the contour of each of the body elements at a point in time  
25 during the procedure as determined by the contour position determining means to the position of the contour of each of the body elements prior to the point in time as represented by the image data subset whereby the contour of the body elements may be determined without the need for exposing the  
30 body elements.

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52. The system of claim 50 wherein the contour position determining means comprises a scanner for determining a position of a contour of each of the body elements during the procedure and wherein the processor  
5 compares the position of the contour of each of the body elements at a point in time during the procedure as determined by the contour position determining means to the position of the contour of each of the body elements prior to the point in time as represented by the image data  
10 subset.

53. The system of claim 51 further comprising a reference array and wherein said ultrasound probe has emitters thereon in communication with the reference array and wherein the contour position determining means  
15 determines the position of the ultrasound probe relative to the reference array whereby the position of the contour of each body element can be determined.

54. The system of claim 51 comprising a reference array having emitters thereon in communication with the  
20 ultrasound probe and wherein the contour position determining means determines the position of the ultrasound probe relative to the reference array whereby the position of the contour of each body element can be determined.

55. The system of claim 52 further comprising a  
25 reference array and wherein said scanner has emitters thereon in communication with the reference array and wherein the contour position determining means determines the position of the scanner relative to the reference array whereby the position of the contour of each body element can  
30 be determined.

56. The system of claim 52 further comprising a reference array having emitters thereon in communication

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with the scanner and wherein the contour position determining means determines the position of the scanner relative to the reference array whereby the position of the contour of each body element can be determined.

5 57. The system of claim 42 further comprising a fluoroscopic device for determining a position of a projection of each of the body elements during the procedure and wherein the processor compares the position of the projection of each of the body elements at a point in time  
10 during the procedure to the position of the projection of each of the body elements prior to the point in time.

58. The system of claim 57 wherein the fluoroscopic device comprises a fluoroscopic tube in fixed relation to a fluoroscopic plate between which the body elements are  
15 located for determining a position of a projection of each of the body elements during the procedure and wherein the processor compares the position of the projection of each of the body elements at a point in time during the procedure to the position of the projection of each of the body elements  
20 prior to the point in time.

59. The system of claim 58 further comprising a reference array and wherein said fluoroscopic tube or said fluoroscopic plate have emitters thereon in communication with the reference array and wherein fluoroscopic device  
25 includes means for determining the position of the tube and plate relative to the reference array whereby the position of the projection of each body element can be determined.

60. The system of claim 58 further comprising a reference array having emitters thereon in communication  
30 with the fluoroscopic tube or the fluoroscopic plate and wherein the fluoroscopic device includes means for determining the position of the tube or plate relative to

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the reference array whereby the position of the projection of each body element can be determined.

61. The system of claim 41 wherein the means for identifying comprises light emitters and at least three  
5 light sensors positioned with respect to the reference points on the particular body element to detect light emitted by the light emitters; and wherein the digitizer positioned to receive a signal output by the light sensors, said digitizer being configured to determine a three  
10 dimensional position of the reference points for the particular body element relative to the light emitters for the other body elements.

62. The system of claim 57 wherein the fluoroscopic device determines a position of a projection of each of the  
15 body elements during the procedure, and the processor compares the position of the projection of each of the body elements at a point in time during the procedure as determined by the fluoroscopic device to the position of the projection of each of the body elements prior to the point  
20 in time as represented by the image data set whereby the projection of the body elements may be determined without the need for exposing the body elements.

63. The system of claim 62 comprising a reference array having emitters or sensors thereon in communication  
25 with the fluoroscopic device and wherein the determining means determines the position of the fluoroscopic device relative to the reference array whereby the position of the projection of each body element can be determined.

64. A system for displaying relative positions of two  
30 or more body elements during a procedure on a body, the system comprising:

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a memory storing an image data set, the image data set representing the position of the body elements based on scans of the body, and having a plurality of data points correlatable to a plurality of reference points for each of  
5 the body elements, the position of reference points of a particular body element relative to the data points for that particular body element being known;

a reference system for identifying, during the procedure, the position of the reference points of each of  
10 the body elements relative to the reference points of the other body elements;

a processor modifying the relative position of the data points of one body element relative to the data points of another body element according to the identified relative  
15 position of the reference points during the procedure as identified by the reference system, the processor generating a displaced image data set representing the position of the body elements during the procedure; and

a display utilizing the displaced image data set  
20 generated by the processor to display the relative position of the body elements during the procedure.

65. The system of claim 64 wherein the reference system comprises a reference frame in communication with a reference array.

25 66. The system of claim 64 further comprising a medical or surgical instrument, wherein the reference system identifies, during the procedure, the position of the instrument relative to at least the body elements, and the display illustrates the position of the instrument relative  
30 to the body elements based on the identified position of the instrument.

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67. A system according to claim 66, wherein the processor monitors the position of the instrument and deactivates it when the monitored position indicates that it is outside a predefined safe zone.

5 68. A system according to claim 66, further comprising robotics to control the position of the instrument and wherein the processor monitors the position of the instrument and instructs the robotics to control it in a predetermined manner.

10 69. A system according to claim 64 wherein the reference system includes emitters for emitting light, sound or electromagnetic radiation and sensors for sensing the emitted light, sound or electromagnetic radiation.

70. The system of claim 65 wherein the reference  
15 system determines an orientation of the instrument relative to the body elements and the display illustrates the orientation of the medical instrument relative to the body elements.

71. The system of claim 65 wherein the reference array  
20 provides a reference, and further comprising a localizer for determining the position of the reference points of the body elements relative to the reference array.

72. The system of claim 71 further comprising a  
registration probe in communication with the reference  
25 array, wherein the localizer determines the position of a tip of the registration probe relative to the reference array and the position of the reference points of the body elements can be determined by positioning the tip of the registration probe at each of the reference points.

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73. The system of claim 65 wherein the position of the reference frame is known in relation to one of the body elements, and the reference system determines the position of the reference frame relative to the reference array so that the body may be moved during the procedure so that the system can determine the position of each of the body elements after movement without re-identifying the relative position of each of the reference points of each of the body elements.

10 74. The system of claim 64 further comprising a processor for discriminating the body elements of the image data set by creating an image data subset defining each of the body elements.

15 75. The system of claim 74 wherein the processor translates each of the image data subsets from the position of the body elements at a point in time to the position of the body elements at a later point in time so that the displaced data set consists of the translated image data subsets.

20 76. The system of claim 64 wherein the reference system determines a position of a contour of each of the body elements during the procedure and wherein the processor compares the position of the contour of each of the body elements at a point in time during the procedure as determined by the device to the position of the contour of each of the body elements prior to the point in time as represented by the image data set.

77. The system of claim 76 wherein the device comprises an ultrasound probe.

30 78. The system of claim 76 wherein the device comprises a scanner.



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79. The system of claim 71 further comprising a fluoroscopic device for determining a position of a projection of each of the body elements during the procedure, wherein the processor compares the position of the projection of each of the body elements at a point in time during the procedure to the position of the projection of each of the body elements prior to the point in time.

80. The system of claim 79 wherein the fluoroscopic device comprises a fluoroscopic tube in fixed relation to a fluoroscopic plate between which the body elements are located.

81. A system for use during a medical or surgical procedure on a body, said system being adapted to generate a display from an image data set representing the position of one or more body elements during the procedure based on scans taken of the body, wherein at least some of the body elements are movable with respect to each other, each scan having a reference for each of the one or more body elements, the reference of a particular body element having a known spatial relation to the particular body element, said system comprising:

a plurality of reference frames, at least one attached to each of the movable body elements;

a localizer for identifying, during the procedure, the position of the reference for each of the body elements to be displayed;

a processor for modifying the image data set according to the identified position of the reference during the procedure, as identified by the localizer, said processor being adapted to generate a displaced image data set representing the position and geometry of the body

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elements according to the identified position of the reference frames during the procedure, as identified by the localizer; and

a display utilizing the displaced image data set  
5 generated by the processor, illustrating the position and geometry of the body elements during the procedure.

82. A system according to claim 81 wherein each of the body elements has a contour having a known spatial relation to the corresponding body element and wherein the reference  
10 relating to each body element comprises the corresponding contour of the body element.

83. A system according to claim 81 wherein each of the body elements has reference points having a known spatial relation to the corresponding body element and wherein the  
15 reference relating to each body element comprises the corresponding reference points of the body element.

84. A system according to claim 83, further comprising a reference array for providing a reference, the localizer being adapted for determining the position of the reference  
20 points for the body elements to be displayed relative to the reference array.

85. A system according to claim 84 wherein the reference frames each have a position in known relation to their associated body element, said reference frames being  
25 adapted to be in communication with the reference array, and wherein the localizer is adapted to determine the position of the reference frames relative to the reference array, the body being movable during the procedure while the body elements remain in fixed relation to their associated  
30 reference frame so that the system can determine the position of each of the body elements after movement without

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again identifying the relative position of each of the reference points for each of the body elements.

86. A system according to claim 84 wherein the reference frames each having a corresponding position in known relation to each of the body elements, said reference frames being adapted to be in communication with the reference array, and wherein the localizer is adapted to determine the position of the reference frames relative to the reference array, the body being movable during the procedure while the body elements remain in known relation to the reference frames so that the system can determine the position of each of the body elements after movement without again identifying the relative position of each of the reference points for each of the body elements.

87. A system according to any one of claims 84-86, wherein the reference array includes one of sensors or emitters and wherein each one of the plurality of reference frames are adapted to be attached to each of the body elements, the plurality of reference frames including the other of sensors or emitters communicating with the emitters or sensors, respectively, of the reference array to indicate the position of the reference frames relative to the reference array.

88. A system according to any one of claims 84-87, wherein the reference array includes sensors and wherein the reference frames are capable of one of continuously and periodically detecting and tracking at least one of the body elements and includes emitters communicating with the sensors of the reference array to indicate the position of the reference frames relative to the reference array.

89. A system according to any one of claims 81-88, further comprising a device for determining a position of a

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contour of each of the body elements during the procedure and wherein the processor is adapted to compare the position of the contour of each of the body elements at a point in time during the procedure as determined by the device to the position of the contour of each of the body elements prior to the point in time as represented by the image data subset.

90. A system according to any one of claims 81-89, wherein the localizer comprises a fluoroscopic device for determining a position of a projection of each of the body elements during the procedure and wherein the processor compares the position of the projection of each of the body elements at a point in time during the procedure to the position of the projection of each of the body elements prior to the point in time.

91. A system according to any one of claims 81-90 wherein at least one of the body elements comprises a semi-rigid body element such as soft tissue.

92. A system according to any one of claims 81-91 wherein the processor modifies the image data set by translation or transformation to generate a displaced image data set representing the position and geometry of the body elements during the procedure.

93. A method for use during a medical or surgical procedure on a body, said method being adapted to generate a display from an image data set representing the position of one or more body elements during the procedure based on scans taken of the body, wherein at least some of the body elements are movable with respect to each other, each scan having a reference for each of the one or more body elements, the reference of a particular body element having a known spatial relation to the particular body element,

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wherein there is a plurality of reference frames, at least one attached to each of the movable body elements; said method comprising the steps of:

identifying, during the procedure, the position of  
5 the reference for each of the body elements to be displayed;

modifying the image data set according to the identified position of the reference during the procedure, as identified by the localizer;

generating a displaced image data set representing  
10 the position and geometry of the body elements according to the identified position of the reference frames during the procedure; and

illustrating the position and geometry of the body elements during the procedure utilizing the displaced image  
15 data set.

94. A method for displaying the relative positions of a plurality of body elements during a procedure on a body, the method comprising:

storing scan images of body elements, the scan  
20 images having a plurality of data points corresponding to a plurality of reference points for each of the body elements, the position of the reference points of a particular body element relative to the data points for that particular body element being known;

25 identifying the position of each of the reference points of each of the body elements relative to the reference points of the other body elements during a procedure;

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modifying the relative position of the data points of one body element relative to the data points of another body element according to the identified relative position of the reference points during the procedure;

5           generating a displaced image data set representing the position of the body elements during the procedure; and

          displaying the relative position of the body elements during the procedure.

95.           The method of claim 94 further comprising  
10   discriminating the contour of the body elements of the image data set and creating an image data subset defining each of the body elements.

96.           The method of claim 95 further comprising scanning  
15   the body elements during the procedure to determine the contour of the body elements and comparing the position of the contour of each of the body elements at a point in time during the procedure to the position of the contour of each of the body elements prior to the point in time as represented by the image data subset.

20   97.           A system according to claim 4, further comprising a plurality of reference frames, each having a corresponding position in known relation to each of the body elements, said reference frames being adapted to be in communication with the reference array, and wherein the localizer is  
25   adapted to determine the position of the reference frames relative to the reference array, the body being movable during the procedure while the body elements remain in known relation to the reference frames so that the system can determine the position of each of the body elements after  
30   movement without again identifying the relative position of each of the reference points for each of the body elements.

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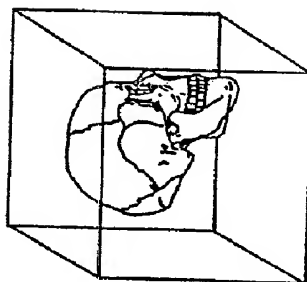
98. A system according to claim 97, wherein the reference array includes sensors and wherein each one of the plurality of reference frames are adapted to be attached to each of the body elements, the plurality of reference frames  
5 including emitters communicating with the sensors of the reference array to indicate the position of the reference frames relative to the reference array.

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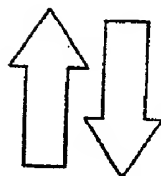
PATENT AGENTS

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FIG. 1  
PRIOR ART



PRE-SURGICAL SCANS  
(IMAGE DATASET)



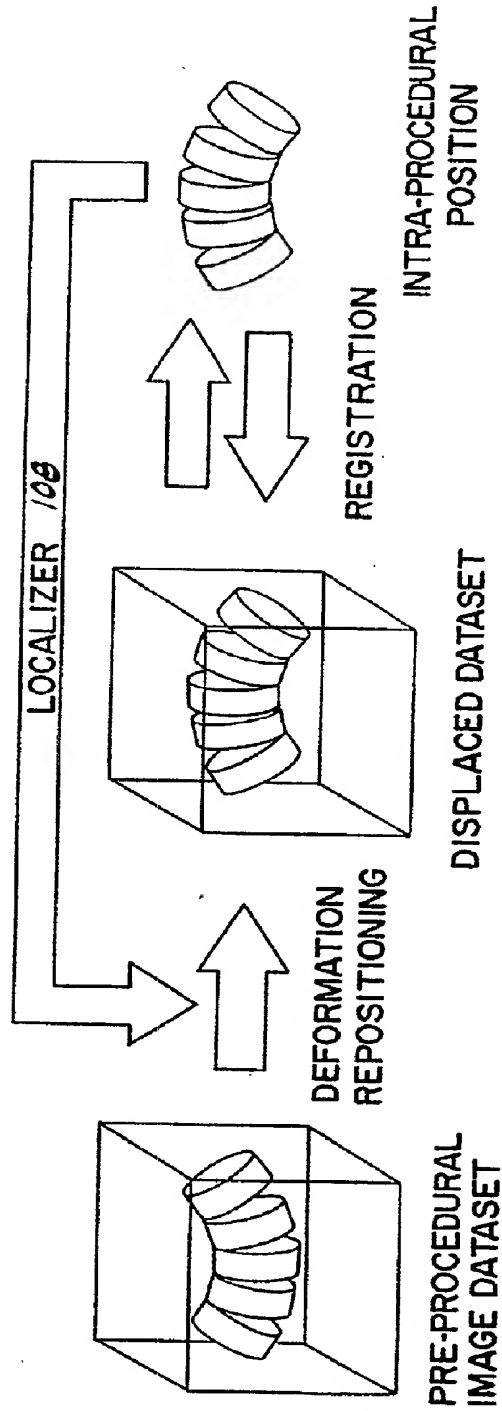
REGISTRATION



POSITION IN  
SURGERY

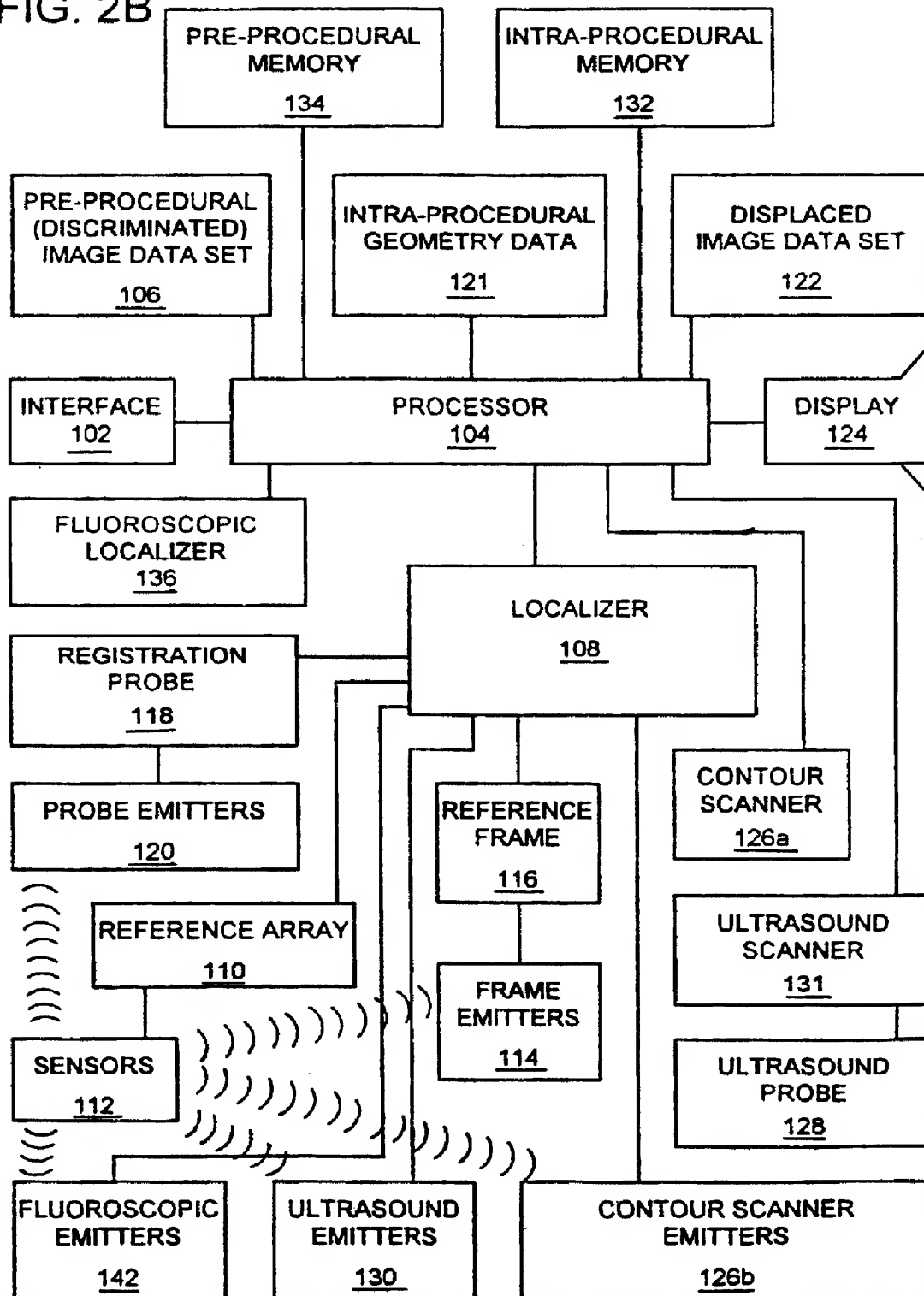


FIG. 2A



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FIG. 2B



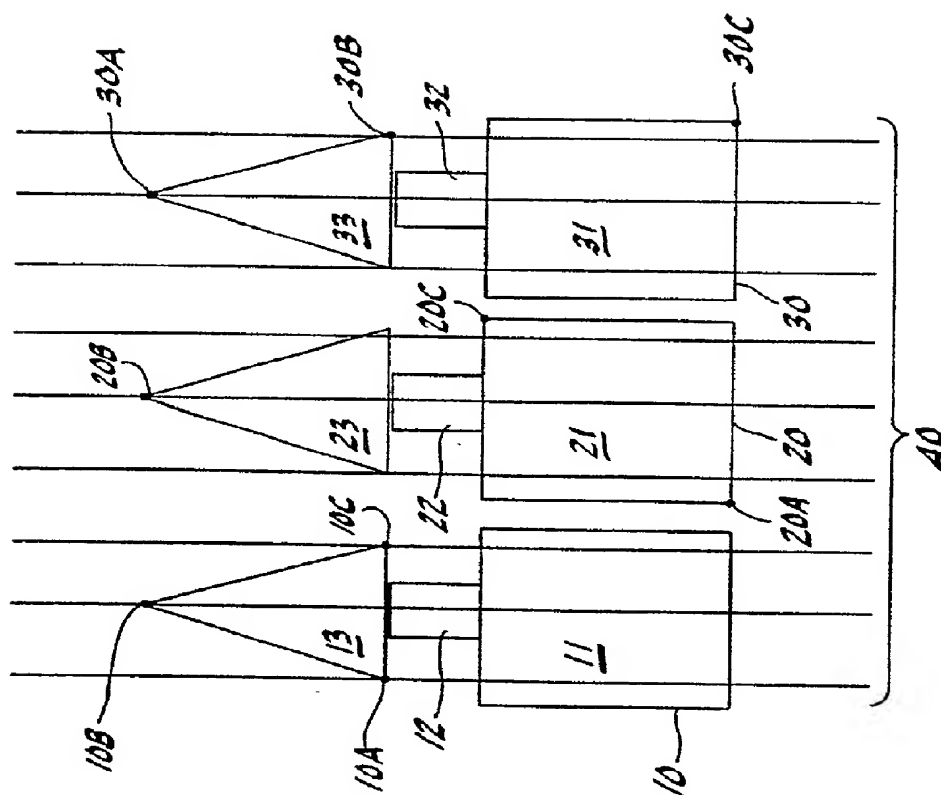
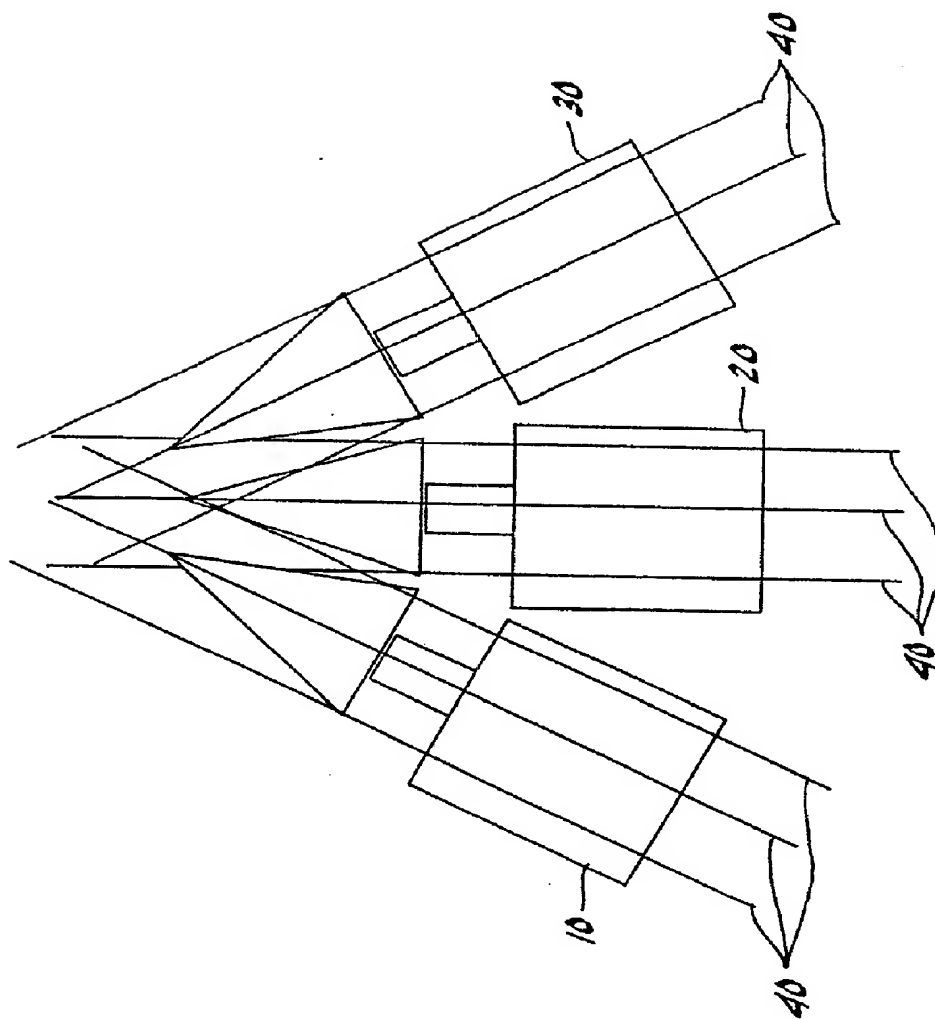


FIG. 3

FIG. 4



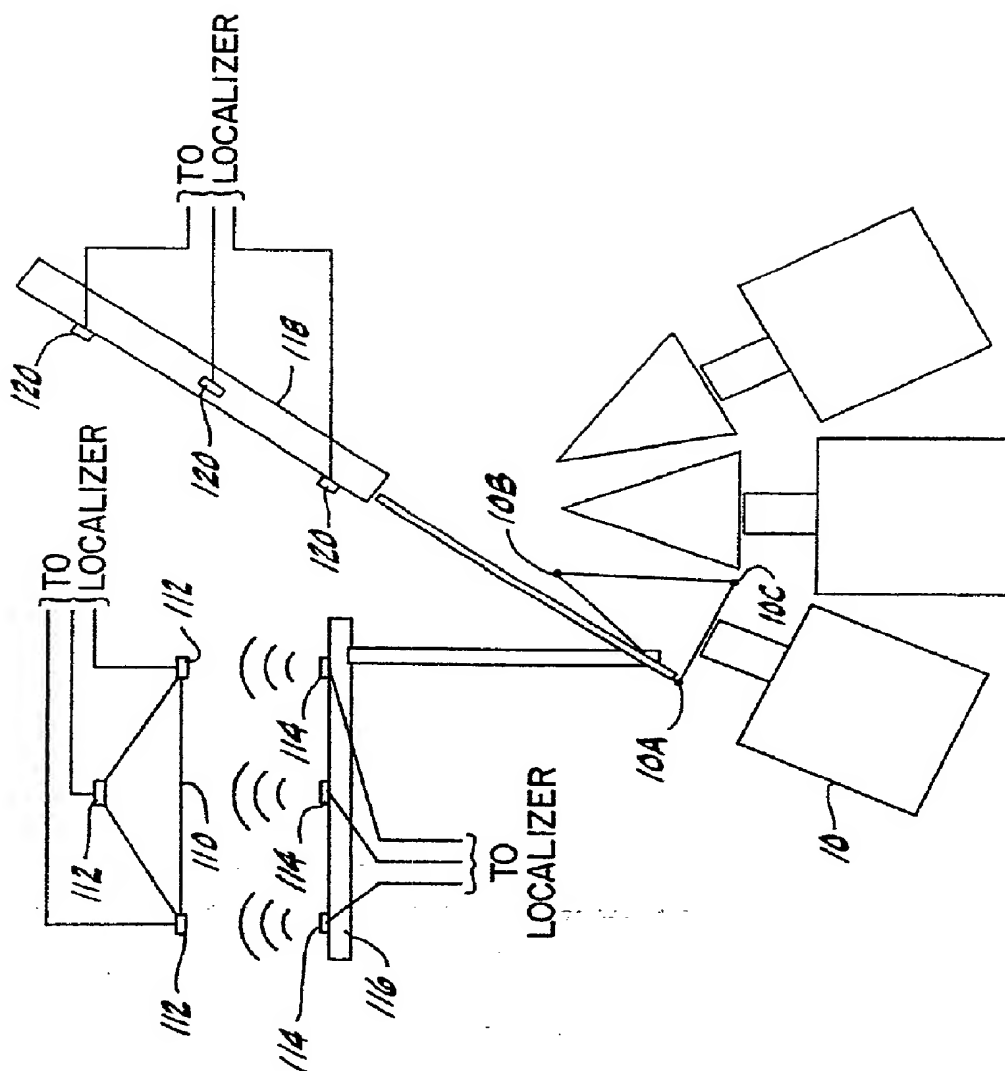
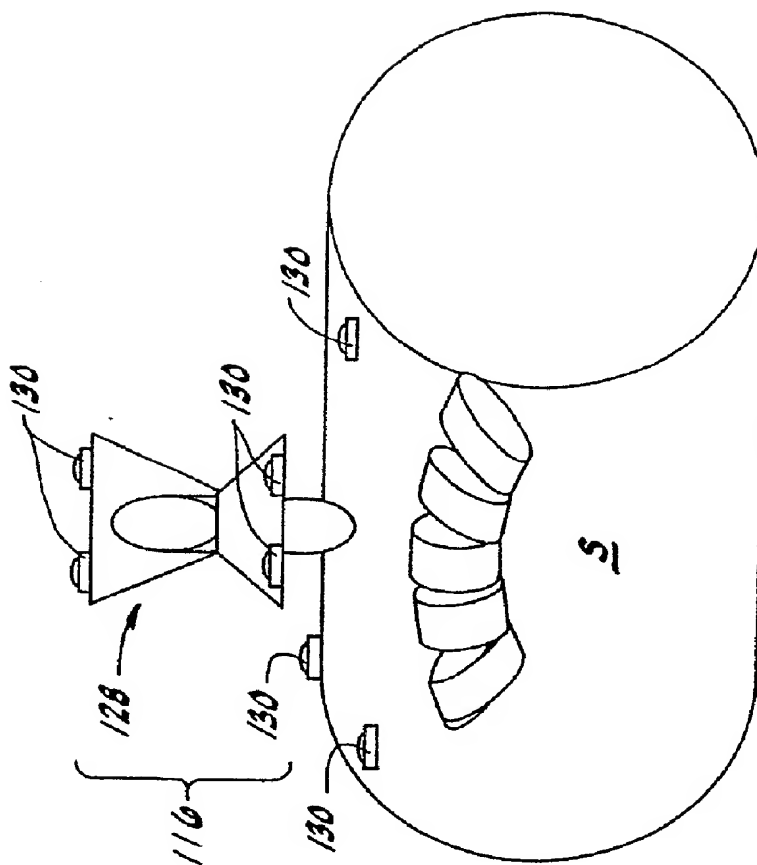
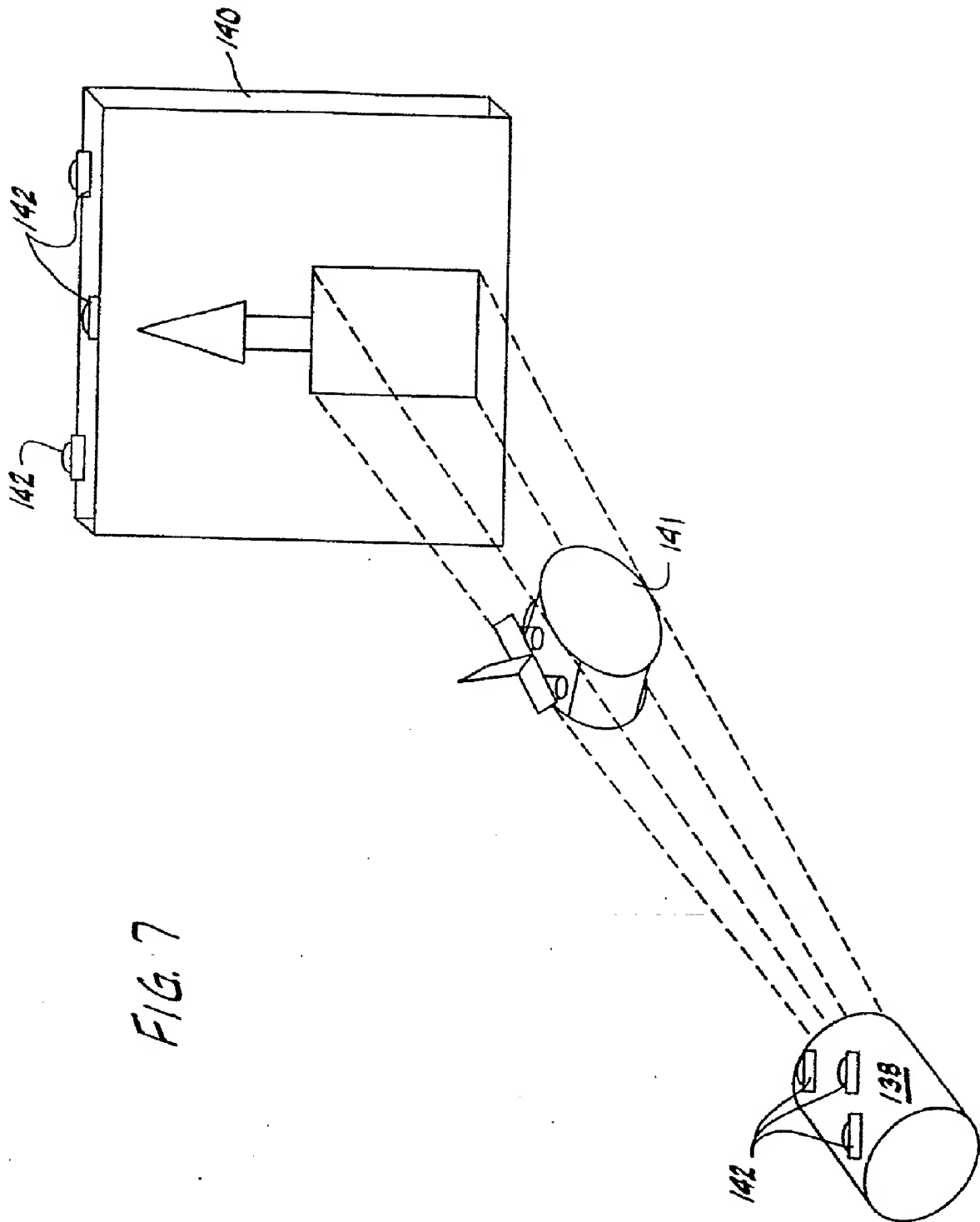


Fig 5

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FIG. 6





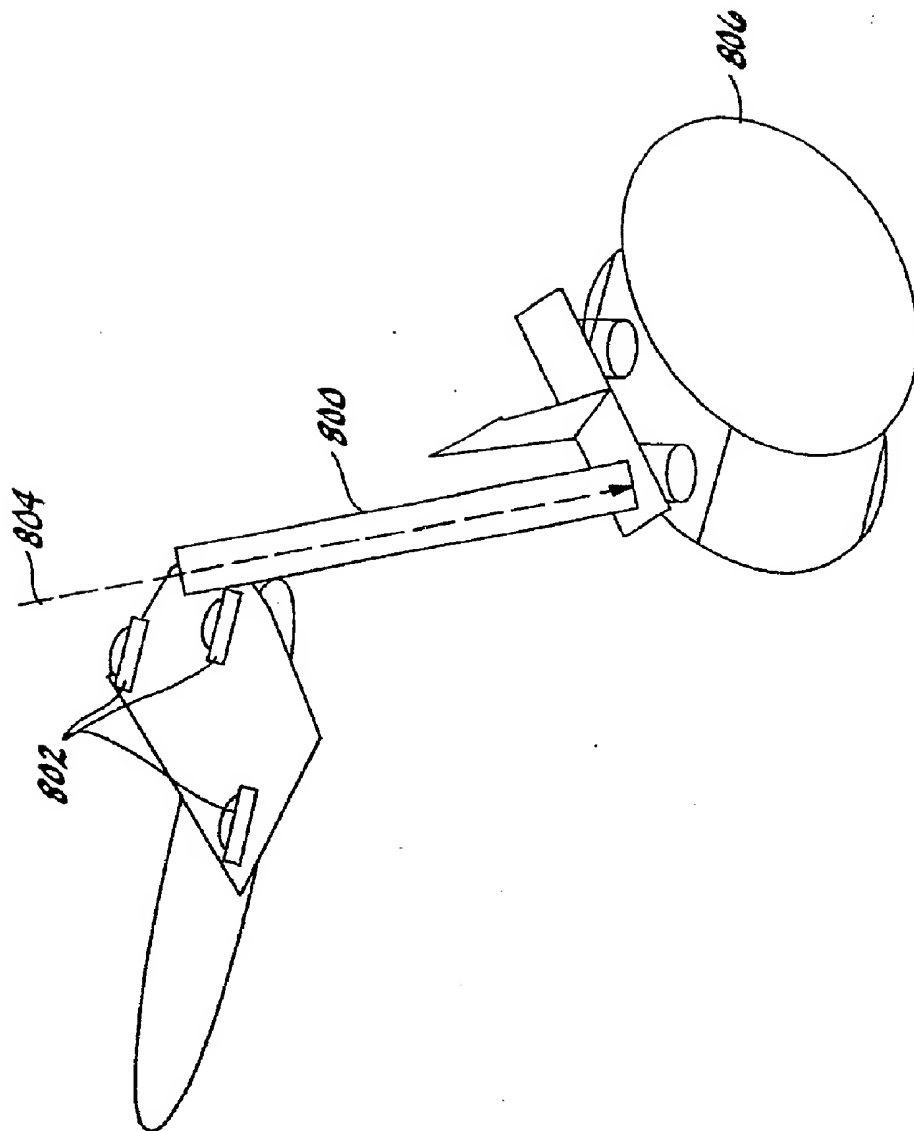
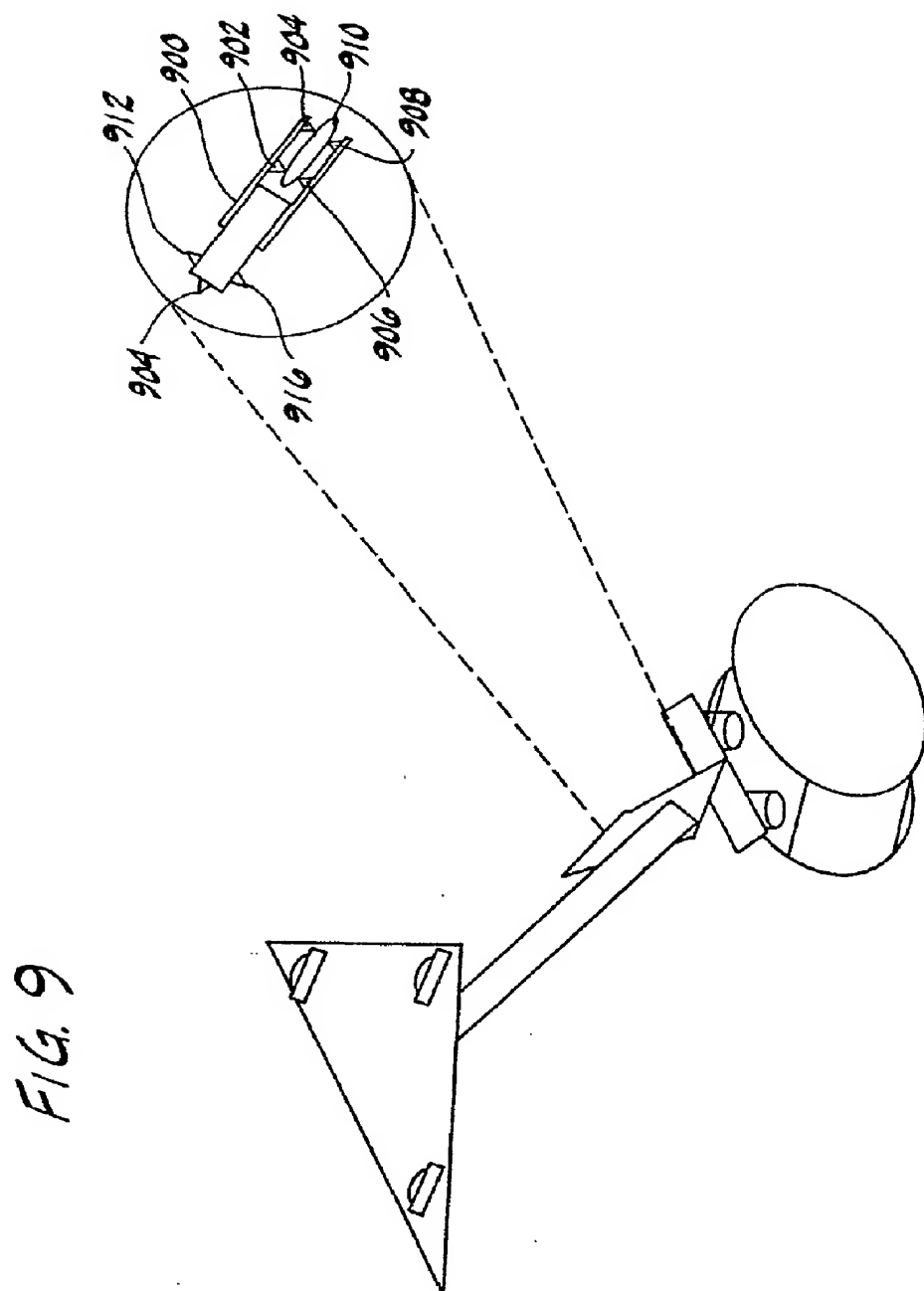


FIG. 8



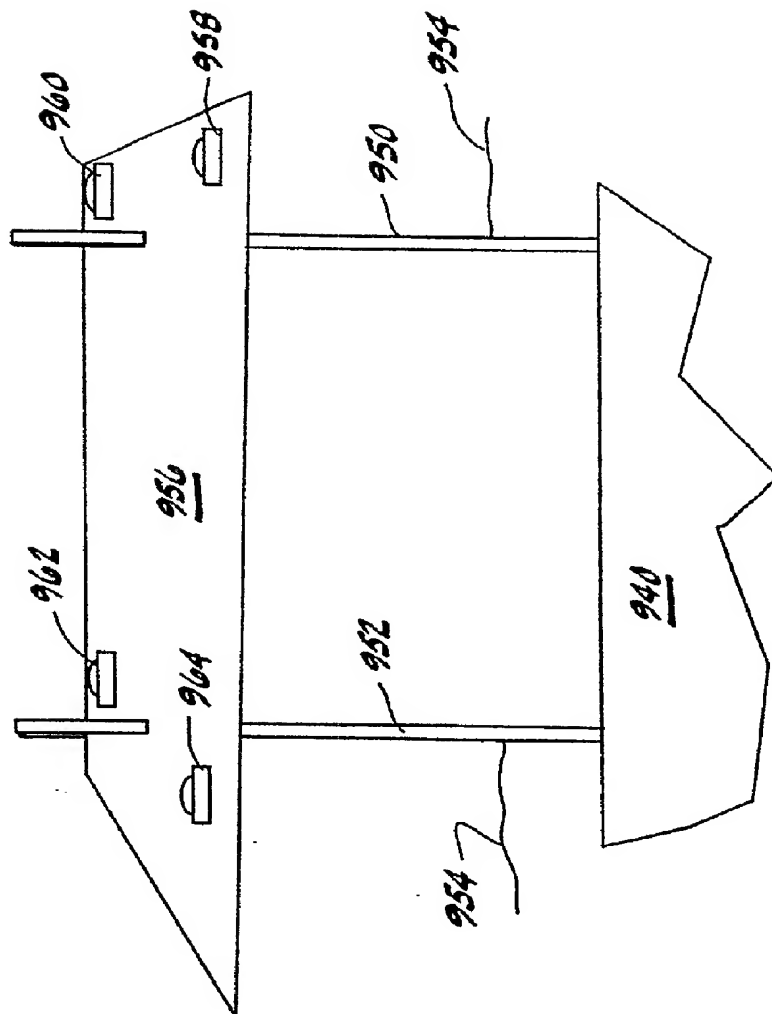
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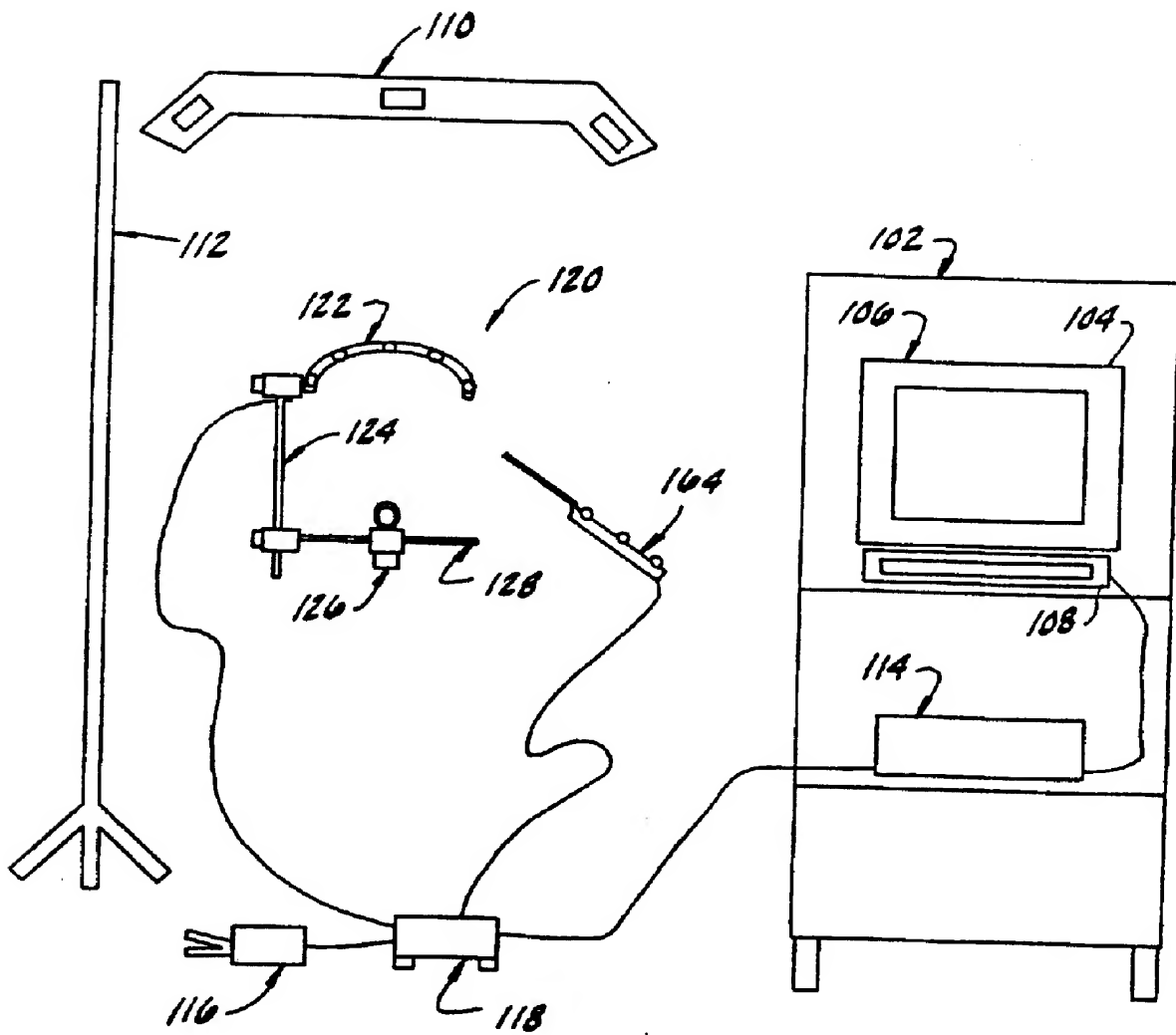
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FIG. 10

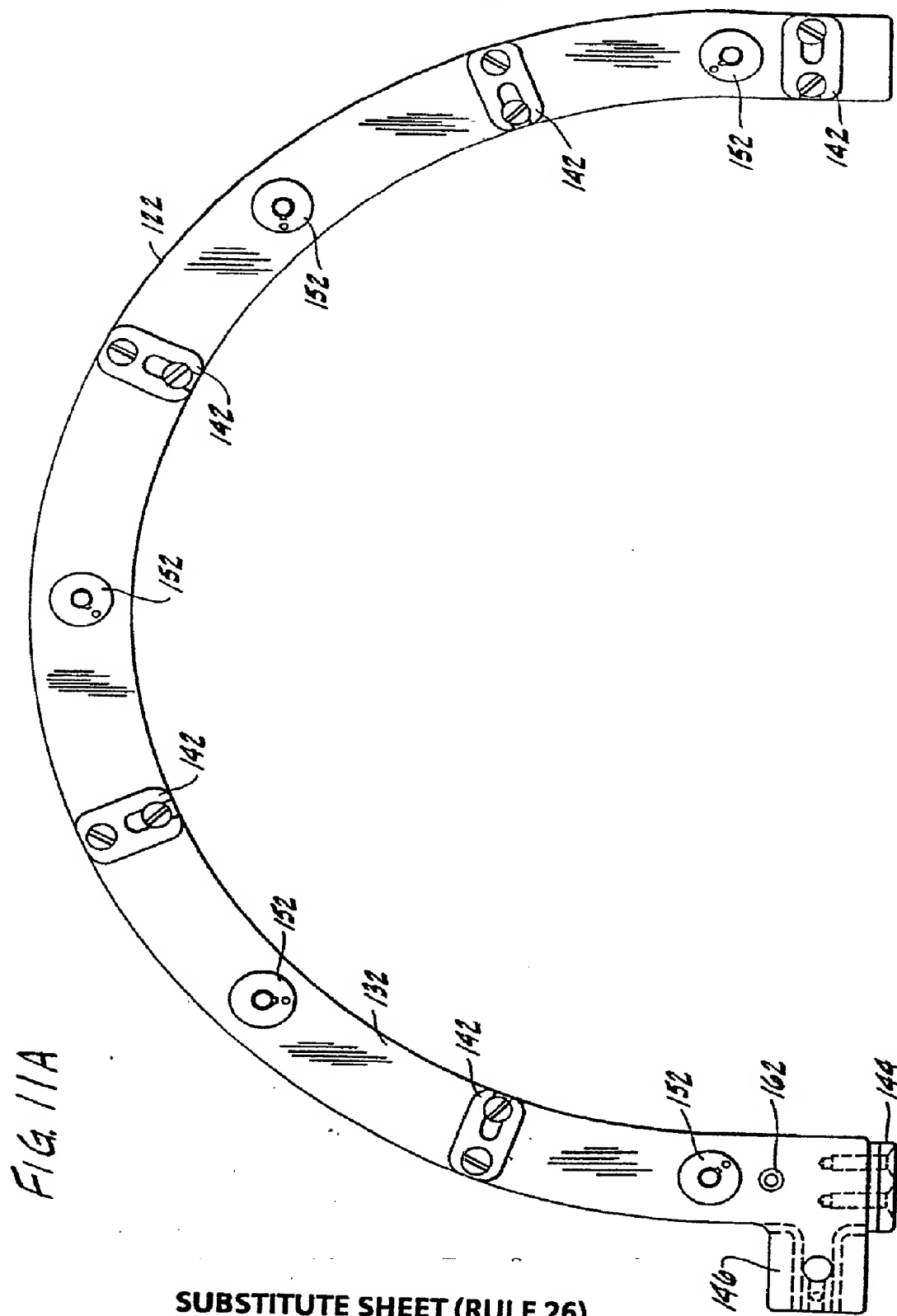


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FIG. 11

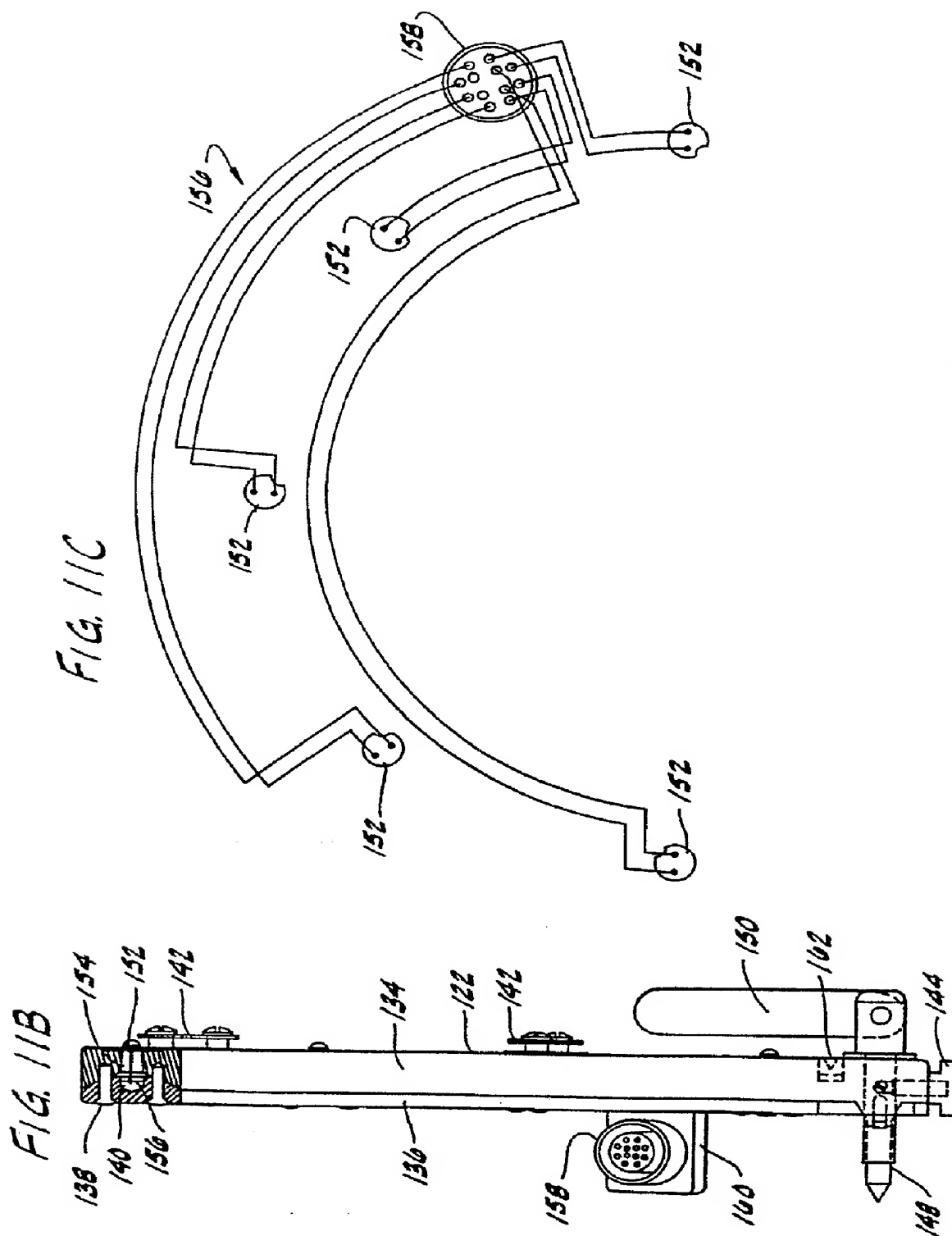


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